BMJ Open

A novel ACT-based video game to support mental health through embedded learning: A mixed-methods feasibility study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041667
Article Type:	Protocol
Date Submitted by the Author:	15-Jun-2020
Complete List of Authors:	Edwards, Darren; Swansea University, ; Swansea Universit Kemp, Andrew; Swansea University, Psychology; Swansea University
Keywords:	Anxiety disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Impulse control disorders < PSYCHIATRY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

A novel ACT-based video game to support mental health through embedded learning: A mixed-methods feasibility study protocol

Darren J. Edwards[1] & Andrew H. Kemp[2]

Department of Public Health, Policy, and Social Sciences, Swansea University, UK[1]

Department of Psychology, Swansea University, UK[2]

Darren J. Edwards,

Department of Public Health, Policy and Social Sciences,

Swansea University,

Swansea,

SA2 8PP,

UK

Email: D.J.Edwards@swansea.ac.uk

Tel: +44 (0)1792 295711

Short title: ACT videogame

Abstract

Introduction: In recent years, serious video games have been utilised to promote emotional regulation in individuals with mental health issues. Though these therapeutic strategies are innovative, they are limited in the scope of treatment, often focusing on specific cognitive skills, to help remediate a specific mental health disorder. **Objective:** Here, a protocol is proposed, which assesses the feasibility of a novel ACT-based video game for young adults. **Methods and analysis:** The MRC framework will be utilised for developing a complex intervention, to design and test the feasibility of an ACT-based video game intervention using a mixed-methods approach involving qualitative and quantitative data. The primary outcomes will include feasibility testing of recruitment processes and the acceptability of the intervention through qualitative interviews, attendance, and rates of attrition. Secondary outcomes will involve a series of quantitative questionnaires to obtain effect sizes for power analysis, allowing for the ideal sample size for a full randomized controlled trial to be determined. **Ethics and Dissemination:** This study has received approval from the College of Human and Health Sciences at Swansea University in the United Kingdom. Dissemination activities will involve publications in peer reviewed journals, presentations at local and national conferences, and promotion through social media.

Strengths and limitations of the study

- Mixed methods approach to build a rich dataset on which conclusions will be drawn
- Protocol follows established medical research council (MRC) guidelines
- In line with MRC guidelines, randomisation is not a component of this study
- Aims are to assess feasibility, an important step in the development of complex interventions, although limiting conclusions

Introduction

Mental health issues such as anxiety and depression are a global problem of increasing concern, imposing considerable burden on society. The Global Burden of Disease project (Whiteford, Ferrari, & Degenhardt, 2016) has identified mental health disorders as a leading cause of disability globally, and suggest that there are 266 million cases of anxiety, and 253 million cases of major depressive disorder globally. Recognition of this issue has led to much innovation in the mental health field over recent years. Some of this innovation has involved technology including telephone, internet, and smartphone devices (Kazdin & Blase, 2011).

Such technological innovation may provide important opportunities for tackling widely reported mental health treatment gaps (Patel et al., 2010) and lags (Wang, Berglund, Olfson, & Kessler, 2004). These issues relate to the gaps between those needing mental health treatment and those able to provide it, and the lags between identifying available support and actually receiving it. Treatment gaps and lags have been estimated to exceed 50% of healthcare needs in all countries around the world and up to 90% in those countries with the least resources, while the treatment lag has been estimated to be as long as 10 years (Alonso et al., 2018; Torres de Galvis et al., 2018). This is a global problem that is compounded by socioeconomic inequalities, such that those with fewest resources have least access to available treatments while often needing them the most (this is known as the 'inverse care law') (Hart, 1971).

Technological developments for tackling such challenges include the exploitation of gamification (Linehan, Kirman, & Roche, 2015). This involves the application of behavioural principles for controlling and modifying human behaviour, in which game design elements are utilised to increase human interaction with or without technology (Deterding, Dixon, Khaled, & Nacke, 2011). Some obvious examples of such gamification include the development of treatment protocols through actual video game development. Some of this

innovation has focused on simple videogames targeting specific deficits, for example, balance training in subacute stroke patients (Morone et al., 2014). Other initiatives have focused on mental health. For instance, recent attempts to gamify the development of cognitive skills and emotional regulation through rewarding the completion of relevant tasks within complex video games (Ducharme et al., 2012; Fernández-Aranda et al., 2012; Hobbs & Yan, 2008; Jiménez-Murcia et al., 2009) in order to promote mental health.

This innovation in video gaming for remediating mental health issues has wide potential application. In the US, over 164 million adults play video games, and at least three quarters of all American families have at least one person who video games regularly (ESA, 2020). In the EU, 54% of the population play videogames between the ages of 6 and 64, where the average age of video gamers is 31, and with a distribution of 46% female and 54% male. Of these, 77% play at least one hour per week, 16% play one hour per month, and 7% play one hour per year (ISFE, 2020). Given that such a large proportion of the Western population play video games, developing mental health training in the form of psychoeducation may have substantial potential applicability for building psychological resilience and helping to better manage depression, anxiety, and other forms of distress.

In low- and middle-income countries (LMIC), however, there is limited data for video-game use. One survey, with a total of 12,000 respondents, conducted in central Asia demonstrated that 8% of females, and 17 % of males in Kyrgyzstan played video games; 18% female, 26% of males in Kazakhstan; 5% female, 18% of males in Tajikistan; and 8% female, 17% of males in Uzbekistan (Kolko & Putnam, 2009). In addition to this, the same study suggested that the information and communications technology (ICT) infrastructure and usage in many developing countries are growing rapidly in these areas, whereby mobile phone use jumped from 20% in 2006 to 64% on 2008. As ICT and downloadable videogame content becomes increasingly available, then these video gaming usage figures will likely rise

in the future for these areas. Interestingly, the 2018 Lancet commission on global mental health suggested that sustainable development of mental health should be an essential component of universal health coverage (Patel et al., 2018). Technological innovation of mental health, in the form of video games, may be one means to achieve this sustainability and a reduction in the treatment gap and lag.

When mental health video games are designed well, they have been shown to elevate self-esteem, self-efficacy, knowledge, and awareness of illness, adherence to treatment, problem solving skills, while lowering aggression (Santamaria et al., 2011). One of the most successful in the facilitation of mental health improvement is a serious video game called PlayMancer (PM), which targets emotional regulation and was specifically designed to help manage impulse control disorders (Fernández-Aranda et al., 2012; Jiménez-Murcia et al., 2009). A 'serious video game' simply means a complex game with multiple levels and settings. The objective of the PM game is to develop emotional and cognitive skills, while reducing impulsivity. The game has been shown to help treat bulimia nervosa by improving emotional regulation (Fagundo et al., 2013; Giner-Bartolomé et al., 2015).

PM also utilises biofeedback (heart rate and heart rate variability) to model physiological and emotional reactions, feeding this information back to the participant. Some research has shown that facilitating awareness of one's own physiology (such as brain activity or cardiac function) enhances the treatment effects of mental health disorders (such as anxiety disorder, depression, OCD, and schizophrenia) via self-regulation (Schoenberg & David, 2014). Biofeedback has also been shown to improve impulse control difficulties, and attentional difficulties in bulimia nervosa and attention deficit hyperactivity disorder (Fagundo et al., 2013; Giner-Bartolomé et al., 2015; Howard, Schellhorn, & Lumsden, 2013), as well as symptoms of stress, anxiety, and anger (Pawlow, O'neil, & Malcolm, 2003). The focus on physiological data in the psychotherapeutic context is gaining traction (Dana, 2018;

Lehrer, 2018; Tulip et al., 2020) and has strong theoretical underpinnings (Kemp, Arias, & Fisher, 2017; Kemp, Koenig, & Thayer, 2017; Mead et al., 2019).

Within PM, there are three mini-games: 'The face of Cronos'; 'Treasures of the sea'; and 'Sign of the Magupta'. Each of these mini-games were designed to train different skills, for example, 'The face of Cronos' and 'Treasures of the sea' develops planning skills, impulse control, coping skills, stress management, and emotional self-regulation, whilst 'Sign of the Magupta' was designed to train relaxation, breathing techniques, and improve physiological, and emotional awareness. However, in the study (Fagundo et al., 2013) PM was combined with sessions of CBT and without a control measure (e.g., CBT only) so the game was developed as an adjunct to traditional mental health training, and there is no real way of knowing what were the direct benefits of the game as opposed to the CBT training. In another study, this time a case study of a single participant playing PM, anxiety, impulsivity, and novelty increasing behaviour did decrease prior to CBT (Giner-Bartolomé et al., 2015). However, this was a case study, and further studies utilising a randomised control trial (RCT) approach are needed to support and provide confidence to these findings.

Another game, Dojo (Scholten, Malmberg, Lobel, Engels, & Granic, 2016), develops emotional regulation in adolescents with anxiety. It uses biofeedback (heart rate variability) and trains breathing techniques, muscle relaxation, positive thinking, and guided imagery to attempt to reduce anxiety in adolescence. It also uses instructional videos and then engages players through immersive and emotionally evocative puzzles that challenge players to use newly acquired emotion regulation skills. However, a pre-post randomized controlled trial (RCT) with 1,347 participants and compared with a standard 'off the shelf 'commercial game 'Rayman 2' as a control, showed that there was no difference between Dojo and the control at reducing anxiety. As both of these significantly reduced anxiety it is likely, therefore, that the reduction in anxiety was possibly due to the games being a distraction from anxiety

provoking thoughts, rather than the development of psychoeducational skills. The authors concluded that crucial design issues need to be carefully thought through, and include a clear theoretical and therapeutic foundation. This includes appropriate methodology which can assess the causes for the improvement, before developing and testing a serious video game for the treatment of mental health issues such as anxiety.

Commercial games (such as Rayman 2) have been explored in their unmodified forms for their effectiveness in helping with social skills training for autism, and cognitive distraction for anxiety and nausea for patients undergoing chemotherapy (Colder Carras et al., 2018), and with some limited success. However, evidence of commercial generalizability outside of the game-playing situation is extremely limited (Griffiths, Kuss, & de Gortari, 2017), and this may be because they act as simple distractions and not therapeutic psychoeducational tools which individuals can apply into their everyday lives. One of the problems with many of these studies is that they often lacked appropriate and rigorous methodology such as longitudinal follow-up (Zayeni, Raynaud, & Revet, 2020), and perhaps mixed-methodological approaches which assess the feasibility and acceptability of such interventions.

Given these concerns, it is perhaps important to note that PM and Dojo's underlying theoretical basis relate to the development of emotional regulation skills. Though emotional regulation has transdiagnostic application (Sloan et al., 2017) (i.e. an intervention designed to treat multiple mental health conditions), their designs do not form part a formal therapeutic behavioural therapy. For instance, PM was used as an adjunct to a second wave behavioural therapy, and Dojo was a stand-alone biofeedback intervention. Our proposed game will have very different theoretical underpinnings, as it will not only be designed to be a comprehensive transdiagnostic intervention, it will integrate a third wave behavioural therapy (as opposed to being an adjunct to) called acceptance and commitment therapy (ACT)

(Hayes, Strosahl, & Wilson, 2009, 2011). It will therefore be comprehensive for the treatment of many common mental health issues such as depression and anxiety and focus on developing clear psychoeducational skills in the form of psychological flexibility, wellbeing, and resilience more generally (Dindo, Van Liew, & Arch, 2017).

The various components and principles of ACT (Hayes et al., 2009, 2011), will be taught within the different chapters of the game and through embedded learning. For example, the player will gain ACT skills while completing objectives within the game and without directly being taught these skills, but rewarded indirectly through points and progress awards. For instance, in one scene (see Table 1) the character is confronted by painful memories, and the player has two choices; (1) to destroy the painful memories; or (2) to accept these memories. If the player chooses to destroy the memories (avoidant based strategies), the world becomes distorted and barriers form making the chapter impossible to complete. Alternatively, if the player chooses acceptance-based strategies they can continue (hence in this scene they learn that acceptance is functionally better than avoidance).

Given this comprehensive transdiagnostic focus on psychological flexibility through ACT – a fundamental component of general health and wellbeing (Kashdan & Rottenberg, 2010), our online videogame may have much greater reach and impact than other serious video games such as PM, Dojo and many of the commercial games available which act as a distractor or restricted forms of emotional regulation for specific conditions. Greater accessibility and impact have important implications for reducing treatment gaps and lags. This may also allow individuals from communities and nations of lower socio-economic backgrounds to have greater access to mental health care.

One reason for choosing ACT in the game development process was pragmatism. For instance, researchers and clinicians may access freely available materials through the

Association of Contextual Behavioural Science (ACBS) website[1], and it does not require formal clinical training or accreditation to practice (Harris, 2009). Given that the principle researcher DE[2] has developed previous ACT-based interventions including an eHealth format (Edwards et al., 2019), there is ample experience in this research team to develop such an intervention effectively.

Another reason for choosing ACT as the basis for the game, is that it has a strong evidence base, and a recent meta-analysis has found it to be efficacious for improving chronic pain, depression, psychotic symptoms, mixed anxiety, OCD, drug abuse, and stress at work (Öst, 2014). This means it is an ideal general purpose therapeutic tool as opposed to just focusing on impulsivity control as, for example, PM had (Fernández-Aranda et al., 2012; Jiménez-Murcia et al., 2009) or simple relaxation skills for adolescence with anxiety, as Dojo had (Scholten et al., 2016).

The ACT principles we use relate to six key properties, which are designed to undermine the trappings of language in the form of difficult thoughts and associated feelings, and promotion of psychological flexibility (Hayes, Strosahl, Bunting, Twohig, & Wilson, 2004). Language trappings can get individuals entangled and can prevent them from engaging with what is truly meaningful to them. The development of psychological flexibility through ACT is important because it is considered to be a fundamental component of well-being (Kashdan & Rottenberg, 2010).

The six ACT processes are: (1) the act of being in the here and now, present and mindful; (Hayes et al., 2011; Strosahl & Wilson, 1999); (2) acceptance, the act of being aware and open to painful thoughts; (3) cognitive fusion, the act of recognising that thoughts are just thoughts and not to buy into them (the process of cognitive defusion) (Hayes, 2005);

[1] https://contextualscience.org/

[2] DE is a Chartered Health Psychologist with the BPS, and a member of ACBS. He has considerable experience in ACT, and has developed several ACT-based interventions.

(4) identifying values, values act as a life compass and direct us towards a life filled with purpose; (5) commitment to values orientation, which is the act of continued work towards values orientation, even when an individual goes off track; (6) self as context (also called the transcendental self), is flexible and transcendent form of self. This involves the awareness of thoughts and feelings but the complete detachment from the literal meaning of thoughts (Kashdan & Rottenberg, 2010).

ACT has been usefully applied to many forms of mental health issues and has been applied in many different forms of delivery. This includes web-based interventions (Edwards et al., 2019; Levin, Haeger, Pierce, & Twohig, 2017; Viskovich & Pakenham, 2018), teleconference (Herbert et al., 2017), and a downloadable app for smartphones (Bricker et al., 2014; Levin, Haeger, Pierce, & Cruz, 2017). So, given the fact that videogames can have positive wellbeing benefits (Johnson, Jones, Scholes, & Carras, 2013; Vella, Johnson, & Hides, 2013), and are applicable for therapeutic purposes (Griffiths et al., 2017; Villani et al., 2018), a transdiagnostic ACT serious video-game may have great potential for similar reasons.

As ACT is a comprehensive transdiagnostic model and formal third wave cognitive-behavioural approach, then its reach and impact in the form of a video game maybe potentially greater than that of PM or Dojo which were based on simpler principle of emotional skills development and biofeedback. In addition to this, as a mobile device video game, like many eHealth applications, this allows those form all socioeconomic backgrounds including those in LMICs to build psychological flexibility and resilience, and ultimately remediate their anxiety and depression, as well as helping close the global problem of a treatment lag and gap. For these reasons, we are proposing an ACT-based video game called 'ACTing Mind' as an innovative and accessible intervention to help individuals who struggle with anxiety, depression, stress, and other forms of distress.

Aims

The research goals of this proposal are to determine the feasibility and acceptability of a novel ACT-based video game intervention for individuals with mental distress, in line with methodology described in the Medical Research Council (MRC) framework (Craig et al., 2019; Craig et al., 2008). This proposal lays the foundation for which a pilot and full RCT will be conducted to determine clinical effectiveness, and ultimately the recommendations of the importance of such innovations in primary care mental health policies and practices.

Methodology

This protocol has been developed following the Template for Intervention Description and Replication of Studies (TIDieR) (Hoffmann et al., 2014) (see appendix 1), as well as the MRC guidelines for the development of complex interventions (Craig et al., 2019; Craig et al., 2008). This includes five stages of development for a complex intervention including: (1) preclinical, involving a theoretical review of the literature (provided here), justifying the need for such an intervention for the proposed population; (2) phase 1, modelling, involving utilizing supportive evidence to determine the components of the underlying mechanisms. For this, we propose a qualitative element involving thematic analysis to enable us to understand what would be most beneficial to a general population with anxiety and depression; (3) phase 2, conducing an exploratory pilot study (outlined here) to determine the feasibility of the methodology and design where some initial data can be collected; (4) phase 3, a randomised controlled trial to test the efficacy of the proposed intervention (RCT) (in subsequent work); (5) phase 4, longer term follow up to assess replicability.

Public and patient involvement

Key stakeholders were consulted and involved in the development of this protocol. The Patient Experience and Evaluation in Research[3] (PEER) group in the College of Human and Health Sciences at Swansea University were consulted. This group represented members of the public, students, and staff members, several of whom reported that they had experienced depression, anxiety, or stress at some point in their lives and emphasised the need for innovative approaches of the delivery of mental health support. The feasibility design was explained to them, and they gave positive feedback about the nature of the design, intervention, and outcome measures.

Study design

This is a mixed methods study which is designed to determine the feasibility and acceptability of an ACT-based video game for individuals with anxiety, depression, and stress, and to increase psychological flexibility.

Study setting

The study will be conducted entirely online, with both the game and questionnaires (through Qualtrics) available online. Thus, the participants can access this freely from their homes. Strict recommendations will require participants to ensure they are in a quiet room and without disruption for the duration of the study.

Recruitment and consent

[3] Patient Experience and Evaluation in Research (PEER): https://www.swansea.ac.uk/humanandhealthsciences/research-at-the-college-of-human-and-health/patientexperienceandevaluationinresearchpeergroup/

We will recruit participants (n = up to 25). Purposive sampling will be used, and while small, the sample size is appropriate given qualitative research seeks to give breadth and depth to data.

Eligibility Criteria

Participants will be recruited through general public mental health forums, social media, and students population. 25 participants will take part in the study. The eligibility criteria include: being 18 years or older, experiences ongoing depression, anxiety, and stress, and being able to read, write and speak English.

Intervention

This ACT-based video videogame intervention called 'ACTing Mind', developed and designed solely by DE, will involve students and members of the public attending 5 one-hour sessions of an ACT-based video game. Each session will involve a different chapter of the videogame, and each chapter will explore a different key component of ACT, with there being six in total (see Table 1 for the different chapters and sessions involved).

The game will start with a depressed individual who has recently lost his wife in an accident, and is feeling depressed, isolated, and lonely (see Figure 1 as an example of this scene). Each chapter will reward ACT consistent behaviour with points on a 'psychoflexameter'. This is a dial on the border of the screen which indicates increased psychological flexibility as the player completes ACT consistent tasks such as acceptance (Chapter 1), being present (Chapter 2), values and commitment (chapter 3), defusion (chapter 4), and self as context (Chapter 5). ACT uses metaphors to help clients visualise the key processes of ACT. In the game, these metaphors are real representations, such as the 'sinking

sand' game, 'dropping the rope' game, the 'chessboard game', the 'unwanted monster' game, the 'leaves on a stream' game (see Table 1).

Within the game, the character will have to enter his own mind through a 'mind escape machine' (see Figure 2 of this as an example of the character in his own mind). At the start of the game, it is explained through a brief historical story that he develops this machine to destroy and supress his unwanted painful thoughts and memories about his wife and loss. Once in his mind, he will learn that destroying or supressing thoughts creates barriers in his mind which prevents him from continuing the game. So, learning acceptance is crucial throughout this game and the character is rewarded for this through points and progress awards. Also, within the game, psychoeducation components explain thoughts as trappings of language which can often get people stuck in life, and prevent them from value consistent living, as well as the various emotional regulation strategies such as avoidance and acceptance.

As part of the study, in addition to playing the video game, participants will be asked to record events on a weekly basis, aspects of application of the ACT principles learned in an everyday life in a journal. It is anticipated that greater adherence to the intervention in everyday life, and engagement with the journal will lead to greater success of the intervention (greater psychological flexibility).

----------Table 1 Here----------

----------Figure 1 Here----------

----------Figure 2 Here----------

Data collection and management

MSc students will be involved in this study and will collect and process the data under supervision by project leads, DJE and AHK. Questionnaires will be completed online through Qualtrics which will store raw data copies, and also be held on an encrypted university server. Names and other personally identifiable information will not be stored, and consent form information will not be associated with the raw or processed data, instead each participant will be given a unique identifier code. Similarity recorded interviewer transcripts will use identifier codes as opposed to personal information (e.g., names). Questionnaire and interview data will be collected at three points in time. The project leads (DJE, AHK) will frequently audit all processes in data collection and processing to ensure that the procedures stated in this protocol are adhered to.

Outcome measures

Questionnaires and will be collected at three points in time (baseline, immediate post intervention, and three-month follow-up). Interview data will be collected immediate post intervention only).

Demographic data

Demographic measures will include age, sex, medication use, as well as intervention feedback, treatment adherence through attrition rates which will all be recorded through Qualtrics and assessed by DE and AH.

Primary outcome measure

The Primary outcomes for feasibility are determined using MRC framework measure for developing a complex intervention (Craig et al., 2019; Craig et al., 2008). As this is a feasibility study, the primary outcomes measure (in accordance with the MRC framework)

includes the acceptability of the ACT-based videogame intervention, the feasibility of the recruitment, outcome measures, and intervention adherence.

Acceptability:

- Number of people dropping out.
- Barriers for adoption of intervention as assessed through interviews.
- Number of sessions attended.
- Time dedicated to home journal.
- ACT principles adherence in everyday life setting (as recorded in journal and expressed through interviews).
- Experience, identifying whether participants had positive experience with the intervention and whether they wanted to continue to be part of the intervention.

Feasibility:

- Number of participants who are willing to take part.
- Time taken to complete questionnaires.
- Number of complete and incomplete questionnaires.

Secondary outcome measures

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) (Tennant et al., 2007): A measure of mental well-being with a focus on positive aspects of mental health. This measure 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 (short-form DASS-21). A short version of this measure and a measure of 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 (Henry & Crawford, 2005).

Social connectedness (adapted from Russell's (1996) UCLA Loneliness Scale (Kok et al., 2013). This measure involves 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." The Cronbach's alpha coefficients for these two items ranged from .80 to .98 (M = .94, SD = .03) (Kok et al., 2013).

EuroQol five dimensions (EQ5D). The EQ5D is a measure for health-related quality of life (HRQOL). There are five components within this measure which assess mobility, self-care, usual activities, pain, discomfort, and anxiety. It also has a visual analogue scale (VAS) for measuring current health status. Scores for these will be calculated for each of these five subsections as well as including the VIS and total EQ5D score of all five subsections. The EQD5 correlates well with other health related questionnaires such as the SF-36 (r = 0.61, p<0.0001) and PDQ-39 (r = -0.75, p<0.0001) (Schrag, Selai, Jahanshahi, & Quinn, 2000).

Acceptance and Action Questionnaire– second version (AAQ-II). This is a 7 item scale developed by Bond et al. (Bond et al., 2011) 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. A higher score indicates higher psychological inflexibility. The measure has good construct validity with a Cronbach's alpha coefficient of 0.84 (Bond et al., 2011).

Sample size and statistical analysis

Sample size recruited will help us determine whether it is possible to recruit sufficient numbers of participants to manage a full-scale RCT at a later date.

Quantitative data analysis: Analysis will focus on descriptive statistics and feasibility outcomes of the questionnaires. While clinical effectiveness will not be formally evaluated at this stage, effect sizes will be explored for early evidence that the intervention shows promising signs (including ACT related process measures). It is predicted that outcomes will improve, and any improvement will be identified using a one-way analysis of variance (ANCOVA) with a single within-subjects factor (time). The effect sizes will also allow for an power calculation to be made which will allow for an approximation for a sample size required in a future trial (if indicated).

Qualitative data analysis: Focus group interview data will be generated through digitally audio-recorded, in-depth, face to face semi-structured interviews (all online and via a password protected room in Zoom). In-depth semi-structured interviews will form the core topics to be discussed (see Table 2), while leaving space and scope for the identification and exploration of unforeseen information that may emerge (Strauss and Corbin 1998).

Thematic analysis will then be conducted which will explore key overarching themes that may emerge from the focus group interviews following standardised guidelines (Braun & Clarke, 2006). The interview questions are based on other novel ACT-based protocols (Edwards et al., 2019; Saracutu, Edwards, Davies, & Rance, 2018). The data will be analysed after the study has been completed. We will follow the inductive and deductive code development as outlined by Fereday and Muir-Cochrane (Fereday & Muir-Cochrane, 2006) to ensure necessary rigor. Any key overarching themes identified which relate to feasibility of the study design of the acceptability of the intervention, as well as potential adverse effects, will be explored and reported.

----------Table 2 Here----------

Ethics and dissemination

Participants will be informed of their rights to confidentiality and to leave the study at any time and without penalty. Both qualitative and quantitative data will be held on a password-protected computer accessible only to researchers DE and AK. The data will be anonymised with a unique identifier code, and any personally identifiable information will be removed.

Dissemination will involve peer-reviewed journals; leading national and international conferences, social media, and public events and through general public health engagement such as talks at schools, the Welsh Government, and engagement with annual science festivals including 'a pint of science'.

Protocol amendments

If the protocol is amended in any way, it will be communicated to relevant parties immediately, such as to participants, journal, and ethics committee.

Ancillary and post-study care

Post-intervention care has not been anticipated given this is a low level (low risk) intervention. Of course, all participants will be given a debrief form which will signpost individuals to the relevant free well-being services such as the Samaritans.

Contributors: DE solely developed the intervention. DE and AK agreed on a set of outcomes. DE wrote the first draft of the protocol and DE and AK then revised the subsequent drafts of the protocol. Both authors helped to revise the manuscript for intellectual content and agreed on the final version prior to submission for peer review.

Funding: The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests: At the time of writing this, DE is discussing with AgorIP at Swansea University the potential to commercialise this video game as a mobile application, however, at this time no agreements have been made or signed. AK has no competing interests.

Data sharing: Data sharing is not applicable as no datasets are generated or analysed for this study.

References

Alonso, J., Liu, Z., Evans-Lacko, S., Sadikova, E., Sampson, N., Chatterji, S., . . . Andrade, L. H. (2018). Treatment gap for anxiety disorders is global: Results of the World Mental Health Surveys in 21 countries. *Depression and Anxiety, 35*(3), 195-208.

Bond, F. W., Hayes, S. C., Baer, R. A., Carpenter, K. M., Guenole, N., Orcutt, H. K., . . . Zettle, R. D. (2011). Preliminary psychometric properties of the Acceptance and Action Questionnaire–II: A revised measure of psychological inflexibility and experiential avoidance. *Behavior therapy, 42*(4), 676-688.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative research in psychology, 3*(2), 77-101.

Bricker, J. B., Mull, K. E., Kientz, J. A., Vilardaga, R., Mercer, L. D., Akioka, K. J., & Heffner, J. L. (2014). Randomized, controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy. *Drug and alcohol dependence, 143*, 87-94.

Colder Carras, M., Van Rooij, A. J., Spruijt-Metz, D., Kvedar, J., Griffiths, M. D., Carabas, Y., & Labrique, A. (2018). Commercial video games as therapy: a new research agenda to unlock the potential of a global pastime. *Frontiers in psychiatry, 8*, 300.

Craig, Dieppe, Macintyre, Michie, Nazareth, & Petticrew. (2019). Developing and evaluating complex interventions: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019. Retrieved from https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/

Craig, Dieppe, Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *Bmj, 337*, a1655.

Dana, D. A. (2018). *The Polyvagal Theory in Therapy: Engaging the Rhythm of Regulation (Norton Series on Interpersonal Neurobiology)*: WW Norton & Company.

Deterding, S., Dixon, D., Khaled, R., & Nacke, L. (2011). *From game design elements to gamefulness: defining" gamification".* Paper presented at the Proceedings of the 15th international academic MindTrek conference: Envisioning future media environments.

Dindo, L., Van Liew, J. R., & Arch, J. J. (2017). Acceptance and commitment therapy: a transdiagnostic behavioral intervention for mental health and medical conditions. *Neurotherapeutics, 14*(3), 546-553.

Ducharme, P., Wharff, E., Hutchinson, E., Kahn, J., Logan, G., & Gonzalez-Heydrich, J. (2012). Videogame assisted emotional regulation training: An ACT with RAGE-Control case illustration. *Clinical Social Work Journal, 40*(1), 75-84.

Edwards, D. J., Rainey, E., Boukouvala, V., Wells, Y., Bennett, P., Tree, J., & Kemp, A. H. (2019). Novel ACT-based eHealth psychoeducational intervention for students with mental distress: a study protocol for a mixed-methodology pilot trial. *BMJ open, 9*(7), e029411.

ESA. (2020). 2019 Essential Facts About the Computer and Video Game Industry. Retrieved from https://www.theesa.com/esa-research/2019-essential-facts-about-the-computer-and-video-game-industry/

Fagundo, A. B., Santamaría, J. J., Forcano, L., Giner-Bartolomé, C., Jiménez-Murcia, S., Sánchez, I., . . . Konstantas, D. (2013). Video game therapy for emotional regulation and impulsivity control in a series of treated cases with bulimia nervosa. *European Eating Disorders Review, 21*(6), 493-499.

Fereday, J., & Muir-Cochrane, E. (2006). Demonstrating rigor using thematic analysis: A hybrid approach of inductive and deductive coding and theme development. *International journal of qualitative methods, 5*(1), 80-92.

Fernández-Aranda, F., Jiménez-Murcia, S., Santamaría, J. J., Gunnard, K., Soto, A., Kalapanidas, E., . . . Granero, R. (2012). Video games as a complementary therapy tool in mental disorders: PlayMancer, a European multicentre study. *Journal of Mental Health, 21*(4), 364-374.

Giner-Bartolomé, C., Fagundo, A. B., Sánchez, I., Jiménez-Murcia, S., Santamaría, J. J., Ladouceur, R., . . . Fernández-Aranda, F. (2015). Can an intervention based on a serious videogame prior to cognitive behavioral therapy be helpful in bulimia nervosa? A clinical case study. *Frontiers in psychology, 6*, 982.

Griffiths, M. D., Kuss, D. J., & de Gortari, A. B. O. (2017). Videogames as therapy: an updated selective review of the medical and psychological literature. *International Journal of Privacy and Health Information Management (IJPHIM), 5*(2), 71-96.

Harris, R. (2009). *ACT made simple: An easy-to-read primer on acceptance and commitment therapy*: New Harbinger Publications.

Hart, J. T. (1971). The inverse care law. *The Lancet, 297*(7696), 405-412.

Hayes. (2005). *Get out of your mind and into your life: The new acceptance and commitment therapy*: New Harbinger Publications.

Hayes, Strosahl, Bunting, Twohig, & Wilson. (2004). What is acceptance and commitment therapy? In *A practical guide to acceptance and commitment therapy* (pp. 3-29): Springer.

Hayes, Strosahl, & Wilson. (2009). *Acceptance and commitment therapy*: American Psychological Association Washington, DC.

Hayes, Strosahl, & Wilson. (2011). *Acceptance and commitment therapy: The process and practice of mindful change*: Guilford Press.

Henry, J. D., & Crawford, J. R. (2005). The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample. *British journal of clinical psychology, 44*(2), 227-239.

Herbert, M. S., Afari, N., Liu, L., Heppner, P., Rutledge, T., Williams, K., . . . Bondi, M. (2017). Telehealth versus in-person acceptance and commitment therapy for chronic pain: a randomized noninferiority trial. *The Journal of Pain, 18*(2), 200-211.

Hobbs, L. J., & Yan, Z. (2008). Cracking the walnut: Using a computer game to impact cognition, emotion, and behavior of highly aggressive fifth grade students. *Computers in Human behavior, 24*(2), 421-438.

Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., . . . Johnston, M. (2014). Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *Bmj, 348*, g1687.

Howard, R., Schellhorn, K., & Lumsden, J. (2013). A biofeedback intervention to control impulsiveness in a severely personality disordered forensic patient. *Personality and mental health, 7*(2), 168-173.

ISFE. (2020). ISFE Key Facts 2019. Retrieved from https://www.isfe.eu/isfe-key-facts/

Jiménez-Murcia, S., Fernández-Aranda, F., Kalapanidas, E., Konstantas, D., Ganchev, T., Kocsis, O., . . . Breiteneder, C. (2009). Playmancer project: a serious videogame as an additional therapy tool for eating and impulse control disorders. In.

Johnson, D., Jones, C., Scholes, L., & Carras, M. C. (2013). Videogames and wellbeing: A comprehensive review.

Kashdan, T. B., & Rottenberg, J. (2010). Psychological flexibility as a fundamental aspect of health. *Clinical psychology review, 30*(7), 865-878.

Kazdin, A. E., & Blase, S. L. (2011). Rebooting psychotherapy research and practice to reduce the burden of mental illness. *Perspectives on Psychological Science, 6*(1), 21-37.

Kemp, Arias, & Fisher. (2017). Social ties, health and wellbeing: a literature review and model. In *Neuroscience and Social Science* (pp. 397-427): Springer.

Kemp, Koenig, & Thayer. (2017). From psychological moments to mortality: a multidisciplinary synthesis on heart rate variability spanning the continuum of time. *Neuroscience & Biobehavioral Reviews, 83*, 547-567.

Kok, B. E., Coffey, K. A., Cohn, M. A., Catalino, L. I., Vacharkulksemsuk, T., Algoe, S. B., . . . Fredrickson, B. L. (2013). How positive emotions build physical health: Perceived positive social connections account for the upward spiral between positive emotions and vagal tone. *Psychological science, 24*(7), 1123-1132.

Kolko, B. E., & Putnam, C. (2009). *Computer games in the developing world: The value of non-instrumental engagement with ICTs, or taking play seriously.* Paper presented at the 2009 International Conference on Information and Communication Technologies and Development (ICTD).

Lehrer, P. M. (2018). Heart rate variability biofeedback and other psychophysiological procedures as important elements in psychotherapy. *International Journal of Psychophysiology, 131*, 89-95.

Levin, Haeger, Pierce, & Twohig. (2017). Web-based acceptance and commitment therapy for mental health problems in college students: A randomized controlled trial. *Behavior Modification, 41*(1), 141-162.

Levin, Haeger, J., Pierce, B., & Cruz, R. A. (2017). Evaluating an adjunctive mobile app to enhance psychological flexibility in acceptance and commitment therapy. *Behavior Modification, 41*(6), 846-867.

Linehan, C., Kirman, B., & Roche, B. (2015). *Gamification as behavioral psychology.* Paper presented at the The gameful world: Approaches, issues, applications.

Mead, J., Fisher, Wilkie, L., Gibbs, K., Pridmore, Tree, J., & Kemp, A. (2019). Rethinking wellbeing: Toward a more ethical science of wellbeing that considers current and future generations.

Morone, G., Tramontano, M., Iosa, M., Shofany, J., Iemma, A., Musicco, M., . . . Caltagirone, C. (2014). The efficacy of balance training with video game-based therapy in subacute stroke patients: a randomized controlled trial. *BioMed research international, 2014*.

Öst, L.-G. (2014). The efficacy of acceptance and commitment therapy: An updated systematic review and meta-analysis. *Behaviour research and therapy, 61*, 105-121.

Patel, V., Maj, M., Flisher, A. J., De Silva, M. J., Koschorke, M., Prince, M., . . . Sanchez, M. (2010). Reducing the treatment gap for mental disorders: a WPA survey. *World Psychiatry, 9*(3), 169-176.

Patel, V., Saxena, S., Lund, C., Thornicroft, G., Baingana, F., Bolton, P., . . . Eaton, J. (2018). The Lancet Commission on global mental health and sustainable development. *The Lancet, 392*(10157), 1553-1598.

Pawlow, L., O'neil, P., & Malcolm, R. (2003). Night eating syndrome: effects of brief relaxation training on stress, mood, hunger, and eating patterns. *International Journal of Obesity, 27*(8), 970-978.

Santamaria, J. J., Soto, A., Fernandez-Aranda, F., Krug, I., Forcano, L., Gunnard, K., . . . Davarakis, C. (2011). Serious games as additional psychological support: A review of the literature. *Journal of CyberTherapy & Rehabilitation (JCR), 4*(4).

Saracutu, M., Edwards, D. J., Davies, H., & Rance, J. (2018). Protocol for a feasibility and acceptability study using a brief ACT-based intervention for people from Southwest Wales who live with persistent pain. *BMJ open, 8*(11), e021866.

Schoenberg, P. L., & David, A. S. (2014). Biofeedback for psychiatric disorders: a systematic review. *Applied psychophysiology and biofeedback, 39*(2), 109-135.

Scholten, H., Malmberg, M., Lobel, A., Engels, R. C., & Granic, I. (2016). A randomized controlled trial to test the effectiveness of an immersive 3D video game for anxiety prevention among adolescents. *PloS one*.

Schrag, A., Selai, C., Jahanshahi, M., & Quinn, N. P. (2000). The EQ-5D—a generic quality of life measure—is a useful instrument to measure quality of life in patients with Parkinson's disease. *Journal of Neurology, Neurosurgery & Psychiatry, 69*(1), 67-73.

Sloan, E., Hall, K., Moulding, R., Bryce, S., Mildred, H., & Staiger, P. K. (2017). Emotion regulation as a transdiagnostic treatment construct across anxiety, depression, substance, eating and borderline personality disorders: A systematic review. *Clinical psychology review, 57*, 141-163.

Strosahl, K., & Wilson, K. (1999). Acceptance and commitment therapy: an experiential approach to behavior change. new york. In: Guilford Press.

Tennant, R., Hiller, L., Fishwick, R., Platt, S., Joseph, S., Weich, S., . . . Stewart-Brown, S. (2007). The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health and Quality of life Outcomes, 5*(1), 63.

Torres de Galvis, Y., Hinkov, H., de Girolamo, G., Chatterji, S., Aguilar-Gaxiola, S., Sampson, N., . . . Bruffaerts, R. (2018). Undertreatment of people with major depressive disorder in 21 countries.

Tulip, C., Fisher, Z., Bankhead, H., Wilkie, L., Pridmore, J., Gracey, F., . . . Kemp, A. H. (2020). Building wellbeing in people with chronic conditions: A qualitative evaluation of an 8-week positive psychotherapy intervention for people living with an acquired brain injury. *Frontiers in psychology, 11*, 66.

Vella, K., Johnson, D., & Hides, L. (2013). *Positively playful: when videogames lead to player wellbeing.* Paper presented at the Proceedings of the First International Conference on Gameful Design, Research, and Applications.

Villani, D., Carissoli, C., Triberti, S., Marchetti, A., Gilli, G., & Riva, G. (2018). Videogames for emotion regulation: a systematic review. *Games for health journal, 7*(2), 85-99.

Viskovich, S., & Pakenham, K. I. (2018). Pilot evaluation of a web-based acceptance and commitment therapy program to promote mental health skills in university students. *J Clin Psychol, 74*(12), 2047-2069. doi:10.1002/jclp.22656

Wang, P. S., Berglund, P. A., Olfson, M., & Kessler, R. C. (2004). Delays in initial treatment contact after first onset of a mental disorder. *Health services research, 39*(2), 393-416.

Whiteford, H., Ferrari, A., & Degenhardt, L. (2016). Global burden of disease studies: implications for mental and substance use disorders. *Health Affairs, 35*(6), 1114-1120.

Zayeni, D., Raynaud, J.-P., & Revet, A. (2020). Therapeutic and Preventive Use of Video Games in Child and Adolescent Psychiatry: A Systematic Review. *Frontiers in psychiatry, 11*, 36.

Figure 1.

First scene in 'ACTing mind', the character, Steve, is depressed and alone.

Figure 2.

An example scene, where the character 'Steve' is in his own mind, and can see his own memories, through his Mindscape machine.

Table 1.
Overview of the 'ACTing Mind' intervention and everyday journal instructions.

Session 1 (week 1) – Acceptance and openness to pain	◆ Chapter 1 – Acceptance ◆ Introducing participants to the videogame and ACT in everyday journal. ◆ A brief overview of the purpose of the program and the content of each session. ◆ Explaining basic ACT tenets through introduction text of journal. ◆ Explaining the nature of painful thoughts and memories and getting caught up in the struggle explained through journal. ◆ Basic story context about the character being depressed and why, at start of videogame. ◆ Explaining the objective of the video game, i.e., to transcend form psychological inflexibility to psychological flexibility. ◆ Exercise, within the game there are choice, either to supress, and break thoughts, or to accept and be open to them. ◆ Acceptance and openness are rewarded by psychological flexibility points on the 'psychoflexameter' and game progression, whilst suppression actions (breaking or supressing painful memories) are punished with physical barriers, and sinking sand, which prevent the player from progressing in the game. ◆ A monster pulls against the player to prevent progress, but if the

	player fights with the monster, they get even more stuck (analogous to the drop the rope and sinking sand metaphor). Again, acceptance is important and must be learned here. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 2 (week 1) - Being present (mindfulness)	◆ Chapter 2 – Being present (mindfulness) ◆ Some instructions form the journal about being present and mindful is given, why it is useful and how to go about achieving with breathing exercises. ◆ The character is approached by monsters in the game in the past and future making him worry excessively about imaginary dangers, and reminding him of painful events. ◆ The game (in the form of the character's wife's ghost) instructs the player to be present, to focus on your breathing for 10 minutes. ◆ As the participant learns and completes relevant psychological flexibility tasks psychological flexibility on the 'psychoflexameter' will increase, which rewards the player for being present. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 3 (week 2)	◆ Chapter 3 – Values identification and commitment ◆ Instructions about what are values (a life compass) explained

– Values identification and commitment	through the journal. ◆ Acceptance and commitment to values orientation as opposed to avoidance behaviour is rewarded. ◆ There are challenges to reach goals which are linked to the character's values, such as scary weather and monsters. ◆ Psychological flexibility on the 'psychoflexameter' and game progress, will increase with values consistent behaviour which rewards the player for committing to values. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 4 (week 2) – Defusion	◆ Chapter 4 – Defusion ◆ Instructions about what is Cognitive fusion and Defusion (holding self-stories lightly) explained through journal. ◆ The character goes back into the 'Mind Escape' machine but this time there is a flowing river with leaves (analogous to leaves on a stream metaphor). ◆ Some of the character's painful memories will beg the player to help them, but if the player interacts, barriers and quicksand appear, punishing the player and preventing them from progressing in the game (analogous to the sinking sand metaphor). ◆ The ghost of the character's wife eventually instructs the player to put the memories and thoughts onto the leaves and watch them flow down the river, without interacting with them, and to simply observe.

	◆ Psychological flexibility on the 'psychoflexameter', will increase when all of the memories and thoughts as left to go down the stream, hence the player is rewarded for defusing. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 5 (week 3) – Self as context	◆ Chapter 5 – Self as context ◆ Instructions about what is self as context (being the observer of your thoughts and not your thought) are explained through journal. ◆ The world starts to fall apart and becomes abstract, like a chess board. The player realises that they are the white pieces on the chessboard (analogous to chess board metaphor). ◆ The player is compelled by the game to beat the black pieces in the chess game. But the more the players fights against the black pieces, the more they lose points on the 'psychoflexameter' and cannot progress in the game. ◆ The player must let the battle paly out, once they do, they become aware that they are the chess board (they become it) and realise they do not need to be part of the never-ending battle between the opposing forces. ◆ Finally, a bus arrives, memories of the character's wife beg the player to stay, and the monsters pull on player. ◆ The player needs to get onto the bus with the monsters to move towards their values, a new beginning (analogues to bus metaphor).

- Finally, the player has a choice, go back, and change the events that led to your wife's death, or stay on the bus with the monsters. Trying to change events leads to a loss in points and prevents game progression. Only staying on the bus, towards values, and accepting the monsters allows the player to complete the game successfully.
- Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.

Table 2
Qualitative interview protocol for the focus groups.

Acceptability and feasibility	How would you describe your experience of taking part in 'ACTing mind' videogame program?
Accessibility of intervention	If this intervention were rolled out as a videogame app, do you think you would download it? Would you appreciate the accessibility?
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 within the game (or applied to your everyday life)?
Suggestions for further improvement	What did you least like about the intervention? What do you think could be improved?
Barriers	Were there any difficulties to taking part?
Implementing change in everday life	Do you practice mindfulness, acceptance, defusion, and values? How often? Could you apply what you have learned through videogame 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 'ACTing Mind'? 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? Was any of it too abstarct or difficult to unbderstand?
Processes of the trial	Was there anything you liked, or disliked about the study? How could we improve this study? 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? Where than any adverse effects that you can recognise due to the intervention?

28x28mm (300 x 300 DPI)

28x28mm (300 x 300 DPI)

TIDieR
Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	8-9	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	8-9	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Table 1	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	12-17, Table 1	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	9	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	12	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	12	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____13, Table 1	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____19____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____19____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_15 (but only to assess adherence and not alter it as this is a feasibility protocol)___	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_N/A (this is a protocol)_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

BMJ Open

A novel ACT-based video game to support mental health through embedded learning: A mixed-methods feasibility study protocol

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2020-041667.R1
Article Type:	Protocol
Date Submitted by the Author:	06-Oct-2020
Complete List of Authors:	Edwards, Darren; Swansea University, ; Swansea Universit Kemp, Andrew; Swansea University, Psychology; Swansea University
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Public health, Health policy
Keywords:	Anxiety disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Impulse control disorders < PSYCHIATRY

I, the Submitting Author has the right to grant and does grant on behalf of all authors of the Work (as defined in the below author licence), an exclusive licence and/or a non-exclusive licence for contributions from authors who are: i) UK Crown employees; ii) where BMJ has agreed a CC-BY licence shall apply, and/or iii) in accordance with the terms applicable for US Federal Government officers or employees acting as part of their official duties; on a worldwide, perpetual, irrevocable, royalty-free basis to BMJ Publishing Group Ltd ("BMJ") its licensees and where the relevant Journal is co-owned by BMJ to the co-owners of the Journal, to publish the Work in this journal and any other BMJ products and to exploit all rights, as set out in our licence.

The Submitting Author accepts and understands that any supply made under these terms is made by BMJ to the Submitting Author unless you are acting as an employee on behalf of your employer or a postgraduate student of an affiliated institution which is paying any applicable article publishing charge ("APC") for Open Access articles. Where the Submitting Author wishes to make the Work available on an Open Access basis (and intends to pay the relevant APC), the terms of reuse of such Open Access shall be governed by a Creative Commons licence – details of these licences and which Creative Commons licence will apply to this Work are set out in our licence referred to above.

Other than as permitted in any relevant BMJ Author's Self Archiving Policies, I confirm this Work has not been accepted for publication elsewhere, is not being considered for publication elsewhere and does not duplicate material already published. I confirm all authors consent to publication of this Work and authorise the granting of this licence.

A novel ACT-based video game to support mental health through embedded learning: A mixed-methods feasibility study protocol

Darren J. Edwards[1] & Andrew H. Kemp[2]

Department of Public Health, Policy, and Social Sciences, Swansea University, UK[1]

Department of Psychology, Swansea University, UK[2]

Darren J. Edwards,

Department of Public Health, Policy and Social Sciences,

Swansea University,

Swansea,

SA2 8PP,

UK

Email: D.J.Edwards@swansea.ac.uk

Tel: +44 (0)1792 295711

Short title: ACT videogame

Abstract

Introduction: In recent years, serious video games have been utilised to promote emotional regulation in individuals with mental health issues. Although these therapeutic strategies are innovative, they are limited with respects to scope of treatment, often focusing on specific cognitive skills, to help remediate a specific mental health disorder. **Objective:** Here we propose a protocol for assessing the feasibility of a novel acceptance and commitment therapy (ACT) based video game for young adults. **Methods and analysis:** The Medical Research Council (MRC) framework will be utilised for developing a complex intervention to design and test the feasibility of an ACT-based video game intervention using a mixed-methods approach involving qualitative and quantitative data. The primary outcomes will include feasibility testing of recruitment processes and the acceptability of the intervention through qualitative interviews, attendance, and rates of attrition. Secondary outcomes will involve a series of quantitative questionnaires to obtain effect sizes for power analysis, allowing for the ideal sample size for an appropriately powered, randomized controlled trial to be determined. **Ethics and Dissemination:** This study has been approved by the Psychology Department Research Ethics Committee (2020-4929-3923) at Swansea University in the United Kingdom. Dissemination activities will involve publications in peer reviewed journals, presentations at local and national conferences, and promotion through social media.

Trial registration number: NCTO4566042 available at Clinicaltrials.Gov

Strengths and limitations of the study

- Mixed methods approach to build a rich dataset on which conclusions will be drawn
- Protocol follows established medical research council (MRC) guidelines

- In line with MRC guidelines and stage of game development, randomisation is not a component of this study
- Aims are to assess feasibility, an important step in the development of complex interventions, although limiting conclusions able to be drawn

Introduction

Mental health issues such as anxiety and depression are a global problem of increasing concern, imposing considerable burden on society. The Global Burden of Disease project [1] has identified mental health disorders as a leading cause of disability globally, and suggest that there are 266 million cases of anxiety, and 253 million cases of major depressive disorder globally.

Unfortunately, the demand for mental health services far exceeds the available human resources able to meet this need in developed and developing countries. This includes ever-growing treatment gaps [2] and lags [3]. These alarming increases have prompted the 2018 Lancet commission on global mental health to suggest that universal health coverage should include efforts to ensure the sustainable development of mental health [4]. Innovations to promote accessibility to mental health treatments include technology such as telephone, internet, and smartphone devices, augmenting the psychotherapeutic toolkit [5].

Innovations in video gaming for remediating mental health issues have wide potential application. In the US, over 164 million adults play video games, and at least three quarters of all American families have at least one person who video games regularly [6]. In the EU, 54% of the population play videogames between the ages of 6 and 64, where the average age of video gamers is 31, and with a distribution of 46% female and 54% male. Of these, 77% play at least one hour per week, 16% play one hour per month, while only 7% play one hour per year [7]. Given that such a large proportion of the Western population play video games, developing mental health training in the form of psychoeducation may have great potential for building psychological resilience and helping to better manage depression, anxiety, and other forms of distress.

Technological developments for tackling such challenges include the exploitation of gamification [8]. This involves the application of behavioural principles for controlling and

modifying human behaviour, in which game design elements are utilised to increase human interaction with or without technology [9]. Some examples of gamification include gamifying the development of cognitive skills and emotional regulation by rewarding the completion of relevant tasks within complex video games [10-13] in order to promote mental health.

When mental health related video games are designed well, they have been shown to elevate self-esteem, self-efficacy, knowledge, and awareness of illness, adherence to treatment and problem solving skills, while lowering aggression [14]. One of the most successful in the facilitation of mental health improvement is a serious video game - a complex game with multiple levels and settings - called PlayMancer (PM), which targets emotional regulation and was specifically designed to help manage impulse control disorders [11, 13]. The objective of the PM game is to develop emotional and cognitive skills, while reducing impulsivity. The game has been shown to help treat bulimia nervosa by improving emotional regulation [15, 16].

PM also utilises biofeedback (heart rate and heart rate variability) to model physiological and emotional reactions, feeding this information back to the participant. Some research has shown that facilitating awareness of one's own physiology (such as brain activity or cardiac function) enhances the treatment effects of mental health disorders (such as anxiety disorder, depression, OCD, and schizophrenia) via self-regulation [17]. Biofeedback has also been shown to improve impulse control difficulties, and attentional difficulties in bulimia nervosa and attention deficit hyperactivity disorder [15, 16, 18], as well as symptoms of stress, anxiety, and anger [19]. The focus on physiological data in the psychotherapeutic context is gaining traction [20-22] and has strong theoretical underpinnings [23-25].

Within PM, there are three mini-games: 'The face of Cronos'; 'Treasures of the sea'; and 'Sign of the Magupta'. Each of these mini-games were designed to train different skills,

for example, 'The face of Cronos' and 'Treasures of the sea' develops planning skills, impulse control, coping skills, stress management, and emotional self-regulation, whilst 'Sign of the Magupta' was designed to train relaxation, breathing techniques, and improve physiological, and emotional awareness. However, in the study [15] PM was combined with sessions of CBT and without a control measure (e.g., CBT only) so the game was developed as an adjunct to traditional mental health training, and there is no real way of knowing the direct benefits of the game as opposed to training in CBT. In another study – a case study of a single participant playing PM – anxiety and impulsivity decreased prior to CBT (Giner-Bartolomé et al., 2015). However, as this study was based on a single case, further studies utilising a randomised control trial (RCT) approach are needed to support and provide confidence to these findings.

Another game, Dojo [26], develops emotional regulation in adolescents with anxiety. It uses biofeedback (heart rate variability) and trains breathing techniques, muscle relaxation, positive thinking, and guided imagery to attempt to reduce anxiety in adolescence. It also uses instructional videos and then engages players through immersive and emotionally evocative puzzles that challenge players to use newly acquired emotion regulation skills. However, a pre-post randomized controlled trial (RCT) with 1,347 participants, compared to a standard 'off the shelf' commercial game 'Rayman 2' (whereby Rayman2 was the control), reported no difference between Dojo and the control condition at reducing anxiety. As both of these games significantly reduced anxiety it is possible that the reduction in anxiety was due distraction from anxiety provoking thoughts, rather than developing psychoeducational skills per se. The authors concluded that crucial design issues need to be carefully thought through, which include a clear theoretical and therapeutic foundation. This includes appropriate methodology that can assess the causes of improvement, before developing and testing a serious video game for the treatment of mental health issues such as anxiety.

Commercial games (such as Rayman 2) have been explored in their unmodified forms for their effectiveness in helping with social skills training for autism, and cognitive distraction for anxiety and nausea for patients undergoing chemotherapy [27], with limited success. Evidence of these games generalizability beyond game-playing is limited [28], and this may be because they act as simple distractions rather than therapeutic psychoeducation applicable to participant's everyday lives. Another issue with many of these studies is that they often lack appropriate and rigorous methodology such as longitudinal follow-up [29], and a mixed-methodological approach that can assess the feasibility and acceptability of such interventions.

Given these issues, it is important to emphasise that the underlying theoretical basis for PM and Dojo relates to the development of emotional regulation skills. While emotional regulation has transdiagnostic application [30] (i.e. an intervention designed to treat multiple mental health conditions), these applications are not underpinned by theoretical frameworks that relate to formal psychotherapeutic interventions. Our proposed game is designed to be a comprehensive transdiagnostic intervention that will integrate a third wave behavioural therapy – as opposed to an adjunct to – acceptance and commitment therapy (ACT) [31, 32]. It will therefore be a comprehensive strategy for managing many common mental health issues such as depression and anxiety and focus on developing clear psychoeducational skills in the form of psychological flexibility, wellbeing, and resilience more generally [33].

Given this comprehensive transdiagnostic focus on psychological flexibility through ACT – a fundamental component of general health and wellbeing [34] – our online videogame may have much greater reach and impact than other serious video games such as PM, Dojo and many of the commercial games which are not based on third wave psychotherapy. Greater accessibility and impact have important implications for reducing

treatment gaps and lags by making more mental health services available to those who need them.

One reason for choosing ACT in the game development process was pragmatism. For instance, researchers and clinicians may access freely available materials through the Association of Contextual Behavioural Science (ACBS) website[1], and it does not require formal clinical training or accreditation to practice [35] which has important implications for translation to video game platforms. Another reason for choosing ACT as the basis for the game, is that it has a strong evidence base, and meta-analysis has found it to be efficacious for improving chronic pain, depression, psychotic symptoms, mixed anxiety, OCD, drug abuse, and stress at work [36]. This means it is an ideal general purpose therapeutic tool as opposed to restricted focus on for example impulsivity control such as the PM application [11, 13] or simple relaxation skills for adolescence with anxiety, as is the focus of the Dojo game [26].

ACT principles are designed to undermine the trappings of language in the form of difficult thoughts and associated feelings, and promotion of psychological flexibility [37]. Language trappings can get individuals entangled and can prevent them from engaging with what is truly meaningful to them. The development of psychological flexibility through ACT is important because it is considered to be a fundamental component of well-being [34].

The six ACT processes are: (1) the act of being in the here and now, present and mindful; [32, 38]; (2) acceptance, the act of being aware and open to painful thoughts; (3) cognitive fusion, the act of recognising that thoughts are just thoughts and not to buy into them (the process of cognitive defusion) [39]; (4) identifying values, values act as a life compass and direct us towards a life filled with purpose; (5) commitment to values orientation, which is the act of continually working towards a values orientation, even when

[1] https://contextualscience.org/

an individual goes off track; (6) self as context (also called the transcendental self), is flexible and transcendent form of self. This involves the awareness of thoughts and feelings but the complete detachment from the literal meaning of thoughts [34].

ACT has been usefully applied to many forms of mental health issues and has been applied in many different forms of delivery. This includes web-based interventions [40-42], teleconference [43], and a downloadable app for smartphones [44, 45]. So, given the fact that videogames can have positive wellbeing benefits [46, 47], and are applicable for therapeutic purposes [28, 48], a transdiagnostic ACT serious video-game may have great potential for similar reasons.

As ACT is a comprehensive transdiagnostic model and formal third wave cognitive-behavioural approach, then its reach and impact in the form of a video game may be greater than that of PM or Dojo which were focused on simpler emotional skills development and biofeedback. For these reasons, we are proposing an ACT-based video game called 'ACTing Mind' as an innovative and accessible intervention to help individuals who struggle with anxiety, depression, stress, and other forms of distress.

Aims

The research goals of this proposal are to determine the feasibility and acceptability of a novel ACT-based video game intervention for individuals with mental distress, in line with methodology described in the Medical Research Council (MRC) framework [49, 50]. This proposal lays the foundation for which a pilot and full-scale RCT will be conducted to determine clinical effectiveness, and ultimately the recommendations of the importance of such innovations in primary care mental health policies and practices.

Methodology

This protocol has been developed following the Template for Intervention Description and Replication of Studies (TIDieR) [51] (see Appendix 1), as well as the MRC guidelines for the development of complex interventions [49, 50]. This includes five stages of development for a complex intervention including: (1) preclinical, involving a theoretical review of the literature (provided here), justifying the need for such an intervention for the proposed population; (2) phase 1, modelling, involving the use of evidence to determine the components for underlying mechanisms. For this, we propose a qualitative element involving thematic analysis to enable us to understand what would be most beneficial to a general population with anxiety and depression; (3) phase 2, conducting an exploratory pilot study (outlined here) to determine the feasibility of the methodology and design where some initial data can be collected; (4) phase 3, a randomised controlled trial to test the efficacy of the proposed intervention (RCT) (in subsequent work); (5) phase 4, longer term follow up to assess replicability.

Public and patient involvement

Key stakeholders were consulted and involved in the development of this protocol. The Patient Experience and Evaluation in Research[2] (PEER) group in the College of Human and Health Sciences at Swansea University were consulted. This group represented members of the public, students, and staff members, several of whom reported that they had experienced depression, anxiety, or stress at some point in their lives and emphasised the need for innovative approaches of the delivery of mental health support. The feasibility design was

[2] Patient Experience and Evaluation in Research (PEER): https://www.swansea.ac.uk/humanandhealthsciences/research-at-the-college-of-human-and-health/patientexperienceandevaluationinresearchpeergroup/

explained to them, and they gave positive feedback about the nature of the design, intervention, and outcome measures.

Study design

This is a mixed methods study which is designed to determine the feasibility and acceptability of an ACT-based video game for individuals with anxiety, depression, and stress, and to increase psychological flexibility.

Study setting

The study will be conducted entirely online including the game and assessment (via the Qualtrics platform), and qualitative interviews (via the Zoom platform). Thus, potential participants will be able to access this study without restrictions, an important consideration for ongoing local lockdowns associated with the COVID-19 pandemic. Strict recommendations will require participants to ensure they are in a quiet room and without disruption for the duration of the study.

Recruitment and consent

We will recruit participants (n = 36) using purposive sampling, focusing on – unlike an opportunity sample – the types of participants needed for a fully randomised controlled trial (i.e. individuals with depression, anxiety, and stress). The sample size is justified on the basis of past research reporting the median numbers of participants recruited for similar types of feasibility studies [52], incorporating both quantitative and qualitative elements.

Eligibility Criteria

Participants will be recruited through general public mental health forums, social media, and student populations. Thirty-six participants will take part in the study and they will be aged 18 years or older, be experiencing ongoing depression, anxiety, and stress, and be able to read, write and speak English.

Intervention

This ACT-based video videogame intervention called 'ACTing Mind', developed and designed solely by DE, will involve students and members of the public attending 5 one-hour sessions of an ACT-based video game. Each session will involve a different chapter of the videogame, and each chapter will explore a different key component of ACT, with there being six in total (see Table 1 for the different chapters and sessions involved).

These various components and principles of ACT [31, 32], will be taught within the different chapters of the game and through embedded learning. For example, the player will gain ACT skills while completing objectives within the game and without directly being taught these skills, but rewarded indirectly through points and progress awards. For instance, in one scene (see Table 1) the character is confronted by painful memories, and the player has two choices; (1) to destroy the painful memories; or (2) to accept these memories. If the player chooses to destroy the memories (avoidant based strategies), the world becomes distorted and barriers form making the chapter impossible to complete. Alternatively, if the player chooses acceptance-based strategies they will be able to continue the game (hence in this scene they learn that acceptance is functionally better than avoidance).

The game will start with a depressed individual who has recently lost his wife in an accident, and is feeling depressed, isolated, and lonely (see Figure 1 as an example of this scene). Each chapter will reward ACT consistent behaviour with points on a 'psychoflexameter'. This is a dial on the border of the screen which indicates increased

psychological flexibility as the player completes ACT-based tasks such as acceptance (Chapter 1), being present (Chapter 2), values and commitment (chapter 3), defusion (chapter 4), and self as context (Chapter 5). ACT uses metaphors to help clients visualise the key processes of ACT. In the game, these metaphors are real representations, such as the 'sinking sand' game, 'dropping the rope' game, the 'chessboard game', the 'unwanted monster' game, the 'leaves on a stream' game (see Table 1).

Within the game, the character will have to enter his own mind through a 'mind escape machine' (see Figure 2 of this as an example of the character in his own mind). At the start of the game, it is explained through a brief historical story that he develops this machine to destroy and supress his unwanted painful thoughts and memories about his wife and loss. Once in his mind, he will learn that destroying or supressing thoughts creates barriers in his mind which prevents him from continuing the game. So, learning acceptance is crucial throughout this game and the character is rewarded for this through points and progress awards. Also, within the game, psychoeducation components explain thoughts as trappings of language which can often get people stuck in life, and prevent them from value consistent living, as well as the various emotional regulation strategies such as avoidance and acceptance.

As part of the study, in addition to playing the video game, participants will be asked to record events on a weekly basis, aspects of application of the ACT principles learned in an everyday life in a journal. It is anticipated that greater adherence to the intervention in everyday life, and engagement with the journal will lead to greater success of the intervention (greater psychological flexibility).

----------Table 1 Here----------

----------Figure 1 Here----------

----------Figure 2 Here----------

Data collection and management

MSc students will have the opportunity to be involved in this study and will collect and process the data under supervision by project leads, DJE and AHK. Questionnaires will be completed online through Qualtrics which will store raw data copies, and also be held on an encrypted university server. Names and other personally identifiable information will not be stored, and consent form information will not be associated with the raw or processed data, instead each participant will be given a unique identifier code. Similarity recorded interviewer transcripts will use identifier codes as opposed to personal information (e.g., names). The project leads (DJE, AHK) will frequently audit all processes in data collection and processing to ensure that the procedures stated in this protocol are adhered to.

Outcome measures

Questionnaires will be collected at three points in time (baseline, immediate post intervention, and three-month follow-up). Interview data will be collected immediate post intervention only.

Demographic data

Demographic measures will include age, sex, medication use, which will all be recorded through Qualtrics and assessed by DE and AH.

Primary outcome measure

The Primary outcomes for feasibility are determined using MRC framework measure for developing a complex intervention [49, 50]. As this is a feasibility study, the primary outcomes (in accordance with the MRC framework) will include the acceptability of the ACT-based videogame intervention, the feasibility of the recruitment, outcome measures, and intervention adherence.

Acceptability:

- Number of people dropping out.
- Barriers for adoption of intervention as assessed through interviews.
- Number of sessions attended.
- Time dedicated to home journal.
- ACT principles adherence in everyday life setting (as recorded in journal and expressed through interviews).
- Experience, identifying whether participants had positive experience with the intervention and whether they wanted to continue to be part of the intervention.

Feasibility:

- Number of participants who are willing to take part.
- Time taken to complete questionnaires.
- Number of complete and incomplete questionnaires.

Secondary outcome measures

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) [53]: A measure of mental well-being with a focus on positive aspects of mental health. This measure 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 (short-form DASS-21). A short version of this measure and a measure of 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 [54].

Social connectedness (adapted from Russell's (1996) UCLA Loneliness Scale [55]. This measure involves two questions; (1) "During social interactions, I feel 'in tune' with the person/s around me", and (2) "During social interactions, I feel close to the person/s." The Cronbach's alpha coefficients for these two items ranged from .80 to .98 (M = .94, SD = .03) [55].

EuroQol five dimensions (EQ5D). The EQ5D is a measure for health-related quality of life (HRQOL). There are five components within this measure which assess mobility, self-care, usual activities, pain, discomfort, and anxiety. It also has a visual analogue scale (VAS) for measuring current health status. Scores for these will be calculated for each of these five subsections as well as including the VIS and total EQ5D score of all five subsections. The EQD5 correlates well with other health related questionnaires such as the SF-36 (r = 0.61, p<0.0001) and PDQ-39 (r = -0.75, p<0.0001) [56].

Acceptance and Action Questionnaire– second version (AAQ-II). This is a 7 item scale developed by Bond et al. [57] 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. A higher score indicates higher psychological inflexibility. The measure has good construct validity with a Cronbach's alpha coefficient of 0.84 [57].

Adherence to the intervention measure and trial

Adherence will be measured in a variety of ways such as intervention feedback, treatment adherence through attrition rates, as well as meta-data of relating to game log-in and log-out, as well as how long the game was played for and what sessions of the game were completed for each participant. Similar information can be recorded in Qualtrics for ensuring questionnaires are completed carefully. This includes length of times completing the questionnaire, and paying attention to reverse-scored questions.

Sample size and statistical analysis

Sample size recruited will help us determine whether it is possible to recruit sufficient numbers of participants to manage a full-scale RCT at a later date.

Quantitative data analysis: Analysis will focus on descriptive statistics and feasibility outcomes of the questionnaires. While clinical effectiveness will not be formally evaluated at this stage, effect sizes will be explored for early evidence that the intervention shows promising signs (including ACT related process measures). It is predicted that outcomes will improve, and any improvement will be identified using a one-way analysis of variance (ANCOVA) with a single within-subjects factor (time). The effect sizes will also allow for an power calculation to be made which will allow for an approximation for a sample size required in a future trial (if indicated).

Qualitative data analysis: Transcripts of focus group interview data will be generated from digital audio-recordings of in-depth, face to face semi-structured interviews (all online and via a password protected room in Zoom). In-depth semi-structured interviews will form the core topics to be discussed (see Table 2), while leaving space and scope for the identification and exploration of unforeseen information that may emerge (Strauss and Corbin 1998).

Insights from this will allow for further development and improvement of the intervention, along with the quantitative data in line with the MRC guidelines [49, 50].

Thematic analysis will then be conducted which will explore key overarching themes that may emerge from the focus group interviews following standardised guidelines [58]. The interview questions are based on other novel ACT-based protocols [40, 59]. The data will be analysed after the study has been completed. We will follow the inductive and deductive code development as outlined by Fereday and Muir-Cochrane [60] to ensure necessary rigor. Any key overarching themes identified which relate to feasibility of the study design of the acceptability of the intervention, as well as potential adverse effects, will be explored and reported.

The focus groups will comprise of 4 to 6 groups with 6 to 10 individuals in each group as has been suggested as optimal in other studies [61]. The interview will take place at the end of the intervention (week 3). It will explore various aspects of the intervention such as perceived process of change, barriers to intervention adherence, trial process, and any adverse effects, which help supplement the quantitative approach. Process of change questions indicate whether the participant learned anything about ACT, and felt any positive change in their life due to participating in the intervention. The question relating to barriers explores any problems and difficulties they had with the intervention. Another question will be asked to elicit suggestions for improvement relating to game or study design. Acceptability questions and process of change in one's life relate to whether the participant accepted the intervention and utilised skills they learned through the intervention in daily life. The question relating to the trial process will determine whether there were any difficulties or limitations of the trial itself such as whether the instructions were clear and how it could be improved. Finally, the question on adverse effects explores whether there were any potential unforeseen negative consequences of the intervention.

----------Table 2 Here----------

Limitations of the study

This study protocol has limitations. Firstly, while physiological measures would ideally be collected to measure variables such as heart rate variability, the COVID-19 pandemic limits our capacity to do this. However, the present study will provide important data on which such measures could be collected, analysed, and interpreted in a future trial. Secondly, it could be questioned why there is no control condition in this study. Our response to this potential criticism is that the aim of the present study is to assess feasibility and – in line with the MRC guidelines [49, 50] – has not been designed to be a fully randomised controlled trial given the current research phase. Once the feasibility component is completed, a control condition will be introduced, which allow for the intervention condition to be compared with control, and as part of a full trial. Finally, although we would like to have ability to monitor the participant more directly, to ensure adherence to the intervention, we are sensitive to privacy issues associated with for example, capturing participants' identity from the computers video camera. To mitigate this limitation, we have opted for less invasive procedures for measuring intervention adherence that will include logging meta-data of the game such as log in and out times, as well as completion of game sections. Several questions in the questionnaire are also reverse scored to ensure participants are paying attention.

Protocol amendments

If the protocol is amended in any way, it will be communicated to relevant parties immediately, such as to participants, journal, and ethics committee.

Ethics and dissemination

This study has received ethical approval from Swansea University Psychology Department ethics committee (2020-4920-3923). Participants will be informed of their rights to confidentiality and to leave the study at any time and without penalty. Both qualitative and quantitative data will be held on a password-protected computer accessible only to researchers DE and AK. The data will be anonymised with a unique identifier code, and any personally identifiable information will be removed.

Dissemination will involve peer-reviewed journals; leading national and international conferences, social media, and public events and through general public health engagement such as talks at schools, the Welsh Government, and engagement with annual science festivals including 'a pint of science'.

Impact of intervention

The potential impact of this study is far reaching as it will add to the growing set of online resources which support psychological resilience, flexibility, and wellbeing. These resources are designed to be easy to access and are ideal for situations where travel is limited due to physical (disability) or situational (coronavirus) immobility. Such interventions can help alleviate widely reported mental health treatment gaps [2] and lags [3], associated with the widely reported scarce human resources needed to provide mental health support for the many individuals who need it. The 2018 Lancet commission on global mental health argued that sustainable development of mental health should be an essential component of universal health coverage [4]. Technological innovation of mental health support services, in the form of video games, may be one means to achieve this sustainability and a reduction in the treatment gap and lag.

Ancillary and post-study care

Post-intervention care has not been anticipated given this is a low level (low risk) intervention. Of course, all participants will be given a debrief form which will signpost individuals to the relevant free well-being services such as the Samaritans.

Contributors: DE developed the intervention. DE and AK agreed on a set of outcomes. DE wrote the first draft of the protocol and DE and AK then revised the subsequent drafts of the protocol. Both authors helped to revise the manuscript for intellectual content and agreed on the final version prior to submission for peer review.

Funding: The authors have not declared a specific grant for this research from any funding agency in the public, commercial (see competing interests) or not-for-profit sectors.

Competing interests: At the time of writing this, DE is discussing with AgorIP at Swansea University the potential to commercialise the described video game as a mobile application, however, at this time no agreements have been made or signed. AK has no competing interests.

Acknowledgements: Many thanks to Prof. Louise McHugh (University College Dublin; UCD) who provided some very helpful feedback about the gamification of an ACT-based approach.

Data sharing: Data sharing is not applicable as no datasets are generated or analysed for this study.

References

1. Whiteford, H., A. Ferrari, and L. Degenhardt, *Global burden of disease studies: implications for mental and substance use disorders.* Health Affairs, 2016. **35**(6): p. 1114-1120.
2. Patel, V., et al., *Reducing the treatment gap for mental disorders: a WPA survey.* World Psychiatry, 2010. **9**(3): p. 169-176.
3. Wang, P.S., et al., *Delays in initial treatment contact after first onset of a mental disorder.* Health services research, 2004. **39**(2): p. 393-416.
4. Patel, V., et al., *The Lancet Commission on global mental health and sustainable development.* The Lancet, 2018. **392**(10157): p. 1553-1598.
5. Kazdin, A.E. and S.L. Blase, *Rebooting psychotherapy research and practice to reduce the burden of mental illness.* Perspectives on psychological science, 2011. **6**(1): p. 21-37.
6. ESA. *2019 Essential Facts About the Computer and Video Game Industry*. 2020; Available from: https://www.theesa.com/esa-research/2019-essential-facts-about-the-computer-and-video-game-industry/.
7. ISFE. *ISFE Key Facts 2019*. 2020; Available from: https://www.isfe.eu/isfe-key-facts/.
8. Linehan, C., B. Kirman, and B. Roche. *Gamification as behavioral psychology*. in *The gameful world: Approaches, issues, applications*. 2015. MIT Press.
9. Deterding, S., et al. *From game design elements to gamefulness: defining" gamification"*. in *Proceedings of the 15th international academic MindTrek conference: Envisioning future media environments*. 2011.
10. Hobbs, L.J. and Z. Yan, *Cracking the walnut: Using a computer game to impact cognition, emotion, and behavior of highly aggressive fifth grade students.* Computers in Human Behavior, 2008. **24**(2): p. 421-438.
11. Jiménez-Murcia, S., et al., *Playmancer project: a serious videogame as an additional therapy tool for eating and impulse control disorders*. 2009.
12. Ducharme, P., et al., *Videogame assisted emotional regulation training: An ACT with RAGE-Control case illustration.* Clinical Social Work Journal, 2012. **40**(1): p. 75-84.
13. Fernández-Aranda, F., et al., *Video games as a complementary therapy tool in mental disorders: PlayMancer, a European multicentre study.* Journal of Mental Health, 2012. **21**(4): p. 364-374.
14. Santamaria, J.J., et al., *Serious games as additional psychological support: A review of the literature.* Journal of CyberTherapy & Rehabilitation (JCR), 2011. **4**(4).
15. Fagundo, A.B., et al., *Video game therapy for emotional regulation and impulsivity control in a series of treated cases with bulimia nervosa.* European Eating Disorders Review, 2013. **21**(6): p. 493-499.
16. Giner-Bartolomé, C., et al., *Can an intervention based on a serious videogame prior to cognitive behavioral therapy be helpful in bulimia nervosa? A clinical case study.* Frontiers in psychology, 2015. **6**: p. 982.
17. Schoenberg, P.L. and A.S. David, *Biofeedback for psychiatric disorders: a systematic review.* Applied psychophysiology and biofeedback, 2014. **39**(2): p. 109-135.
18. Howard, R., K. Schellhorn, and J. Lumsden, *A biofeedback intervention to control impulsiveness in a severely personality disordered forensic patient.* Personality and mental health, 2013. **7**(2): p. 168-173.
19. Pawlow, L., P. O'neil, and R. Malcolm, *Night eating syndrome: effects of brief relaxation training on stress, mood, hunger, and eating patterns.* International Journal of Obesity, 2003. **27**(8): p. 970-978.

20. Dana, D.A., *The Polyvagal Theory in Therapy: Engaging the Rhythm of Regulation (Norton Series on Interpersonal Neurobiology)*. 2018: WW Norton & Company.
21. Lehrer, P.M., *Heart rate variability biofeedback and other psychophysiological procedures as important elements in psychotherapy.* International Journal of Psychophysiology, 2018. **131**: p. 89-95.
22. Tulip, C., et al., *Building wellbeing in people with chronic conditions: A qualitative evaluation of an 8-week positive psychotherapy intervention for people living with an acquired brain injury.* Frontiers in psychology, 2020. **11**: p. 66.
23. Kemp, Koenig, and Thayer, *From psychological moments to mortality: a multidisciplinary synthesis on heart rate variability spanning the continuum of time.* Neuroscience & Biobehavioral Reviews, 2017. **83**: p. 547-567.
24. Mead, J., et al., *Rethinking wellbeing: Toward a more ethical science of wellbeing that considers current and future generations.* 2019.
25. Kemp, Arias, and Fisher, *Social ties, health and wellbeing: a literature review and model*, in *Neuroscience and Social Science*. 2017, Springer. p. 397-427.
26. Scholten, H., et al., *A randomized controlled trial to test the effectiveness of an immersive 3D video game for anxiety prevention among adolescents.* PloS one, 2016.
27. Colder Carras, M., et al., *Commercial video games as therapy: a new research agenda to unlock the potential of a global pastime.* Frontiers in psychiatry, 2018. **8**: p. 300.
28. Griffiths, M.D., D.J. Kuss, and A.B.O. de Gortari, *Videogames as therapy: an updated selective review of the medical and psychological literature.* International Journal of Privacy and Health Information Management (IJPHIM), 2017. **5**(2): p. 71-96.
29. Zayeni, D., J.-P. Raynaud, and A. Revet, *Therapeutic and Preventive Use of Video Games in Child and Adolescent Psychiatry: A Systematic Review.* Frontiers in Psychiatry, 2020. **11**: p. 36.
30. Sloan, E., et al., *Emotion regulation as a transdiagnostic treatment construct across anxiety, depression, substance, eating and borderline personality disorders: A systematic review.* Clinical psychology review, 2017. **57**: p. 141-163.
31. Hayes, Strosahl, and Wilson, *Acceptance and commitment therapy*. 2009: American Psychological Association Washington, DC.
32. Hayes, Strosahl, and Wilson, *Acceptance and commitment therapy: The process and practice of mindful change*. 2011: Guilford Press.
33. Dindo, L., J.R. Van Liew, and J.J. Arch, *Acceptance and commitment therapy: a transdiagnostic behavioral intervention for mental health and medical conditions.* Neurotherapeutics, 2017. **14**(3): p. 546-553.
34. Kashdan, T.B. and J. Rottenberg, *Psychological flexibility as a fundamental aspect of health.* Clinical psychology review, 2010. **30**(7): p. 865-878.
35. Harris, R., *ACT made simple: An easy-to-read primer on acceptance and commitment therapy*. 2009: New Harbinger Publications.
36. Öst, L.-G., *The efficacy of acceptance and commitment therapy: An updated systematic review and meta-analysis.* Behaviour research and therapy, 2014. **61**: p. 105-121.
37. Hayes, et al., *What is acceptance and commitment therapy?*, in *A practical guide to acceptance and commitment therapy*. 2004, Springer. p. 3-29.
38. Strosahl, K. and K. Wilson, *Acceptance and commitment therapy: an experiential approach to behavior change. new york*. 1999, Guilford Press.
39. Hayes, *Get out of your mind and into your life: The new acceptance and commitment therapy*. 2005: New Harbinger Publications.
40. Edwards, D.J., et al., *Novel ACT-based eHealth psychoeducational intervention for students with mental distress: a study protocol for a mixed-methodology pilot trial.* BMJ open, 2019. **9**(7): p. e029411.

41. Viskovich, S. and K.I. Pakenham, *Pilot evaluation of a web-based acceptance and commitment therapy program to promote mental health skills in university students.* J Clin Psychol, 2018. **74**(12): p. 2047-2069.
42. Levin, et al., *Web-based acceptance and commitment therapy for mental health problems in college students: A randomized controlled trial.* Behavior Modification, 2017. **41**(1): p. 141-162.
43. Herbert, M.S., et al., *Telehealth versus in-person acceptance and commitment therapy for chronic pain: a randomized noninferiority trial.* The Journal of Pain, 2017. **18**(2): p. 200-211.
44. Bricker, J.B., et al., *Randomized, controlled pilot trial of a smartphone app for smoking cessation using acceptance and commitment therapy.* Drug and alcohol dependence, 2014. **143**: p. 87-94.
45. Levin, et al., *Evaluating an adjunctive mobile app to enhance psychological flexibility in acceptance and commitment therapy.* Behavior modification, 2017. **41**(6): p. 846-867.
46. Johnson, D., et al., *Videogames and wellbeing: A comprehensive review.* 2013.
47. Vella, K., D. Johnson, and L. Hides. *Positively playful: when videogames lead to player wellbeing*. in *Proceedings of the First International Conference on Gameful Design, Research, and Applications*. 2013.
48. Villani, D., et al., *Videogames for emotion regulation: a systematic review.* Games for health journal, 2018. **7**(2): p. 85-99.
49. Craig, et al. *Developing and evaluating complex interventions: Following considerable development in the field since 2006, MRC and NIHR have jointly commissioned an update of this guidance to be published in 2019*. 2019; Available from: https://mrc.ukri.org/documents/pdf/complex-interventions-guidance/.
50. Craig, et al., *Developing and evaluating complex interventions: the new Medical Research Council guidance.* Bmj, 2008. **337**: p. a1655.
51. Hoffmann, T.C., et al., *Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide.* Bmj, 2014. **348**: p. g1687.
52. Billingham, S.A., A.L. Whitehead, and S.A. Julious, *An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom Clinical Research Network database.* BMC medical research methodology, 2013. **13**(1): p. 104.
53. Tennant, R., et al., *The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation.* Health and Quality of life Outcomes, 2007. **5**(1): p. 63.
54. Henry, J.D. and J.R. Crawford, *The short-form version of the Depression Anxiety Stress Scales (DASS-21): Construct validity and normative data in a large non-clinical sample.* British journal of clinical psychology, 2005. **44**(2): p. 227-239.
55. Kok, B.E., et al., *How positive emotions build physical health: Perceived positive social connections account for the upward spiral between positive emotions and vagal tone.* Psychological science, 2013. **24**(7): p. 1123-1132.
56. Schrag, A., et al., *The EQ-5D—a generic quality of life measure—is a useful instrument to measure quality of life in patients with Parkinson's disease.* Journal of Neurology, Neurosurgery & Psychiatry, 2000. **69**(1): p. 67-73.
57. Bond, F.W., et al., *Preliminary psychometric properties of the Acceptance and Action Questionnaire–II: A revised measure of psychological inflexibility and experiential avoidance.* Behavior therapy, 2011. **42**(4): p. 676-688.
58. Braun, V. and V. Clarke, *Using thematic analysis in psychology.* Qualitative research in psychology, 2006. **3**(2): p. 77-101.
59. Saracutu, M., et al., *Protocol for a feasibility and acceptability study using a brief ACT-based intervention for people from Southwest Wales who live with persistent pain.* BMJ open, 2018. **8**(11): p. e021866.

60. Fereday, J. and E. Muir-Cochrane, *Demonstrating rigor using thematic analysis: A hybrid approach of inductive and deductive coding and theme development.* International journal of qualitative methods, 2006. **5**(1): p. 80-92.
61. Morgan, D.L., *Focus groups.* Annual review of sociology, 1996. **22**(1): p. 129-152.

Figure 1.

First scene in ‘ACTing mind’, the character, Steve, is depressed and alone.

Figure 2.

An example scene, where the character ‘Steve’ is in his own mind, and can see his own memories, through his Mindscape machine.

Table 1.
Overview of the 'ACTing Mind' intervention and everyday journal instructions.

Session 1 (week 1) – Acceptance and openness to pain	◆ Chapter 1 – Acceptance ◆ Introducing participants to the videogame and ACT in everyday journal. ◆ A brief overview of the purpose of the program and the content of each session. ◆ Explaining basic ACT tenets through introduction text of journal. ◆ Explaining the nature of painful thoughts and memories and getting caught up in the struggle explained through journal. ◆ Basic story context about the character being depressed and why, at start of videogame. ◆ Explaining the objective of the video game, i.e., to transcend form psychological inflexibility to psychological flexibility. ◆ Exercise, within the game there are choice, either to supress, and break thoughts, or to accept and be open to them. ◆ Acceptance and openness are rewarded by psychological flexibility points on the 'psychoflexameter' and game progression, whilst suppression actions (breaking or supressing painful memories) are punished with physical barriers, and sinking sand, which prevent the player from progressing in the game. ◆ A monster pulls against the player to prevent progress, but if the

	player fights with the monster, they get even more stuck (analogous to the drop the rope and sinking sand metaphor). Again, acceptance is important and must be learned here. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 2 (week 1) - Being present (mindfulness)	◆ Chapter 2 – Being present (mindfulness) ◆ Some instructions form the journal about being present and mindful is given, why it is useful and how to go about achieving with breathing exercises. ◆ The character is approached by monsters in the game in the past and future making him worry excessively about imaginary dangers, and reminding him of painful events. ◆ The game (in the form of the character's wife's ghost) instructs the player to be present, to focus on your breathing for 10 minutes. ◆ As the participant learns and completes relevant psychological flexibility tasks psychological flexibility on the 'psychoflexameter' will increase, which rewards the player for being present. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 3 (week 2)	◆ Chapter 3 – Values identification and commitment ◆ Instructions about what are values (a life compass) explained

– Values identification and commitment	through the journal. ◆ Acceptance and commitment to values orientation as opposed to avoidance behaviour is rewarded. ◆ There are challenges to reach goals which are linked to the character's values, such as scary weather and monsters. ◆ Psychological flexibility on the 'psychoflexameter' and game progress, will increase with values consistent behaviour which rewards the player for committing to values. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 4 (week 2) – Defusion	◆ Chapter 4 – Defusion ◆ Instructions about what is Cognitive fusion and Defusion (holding self-stories lightly) explained through journal. ◆ The character goes back into the 'Mind Escape' machine but this time there is a flowing river with leaves (analogous to leaves on a stream metaphor). ◆ Some of the character's painful memories will beg the player to help them, but if the player interacts, barriers and quicksand appear, punishing the player and preventing them from progressing in the game (analogous to the sinking sand metaphor). ◆ The ghost of the character's wife eventually instructs the player to put the memories and thoughts onto the leaves and watch them flow down the river, without interacting with them, and to simply observe.

	◆ Psychological flexibility on the 'psychoflexameter', will increase when all of the memories and thoughts as left to go down the stream, hence the player is rewarded for defusing. ◆ Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.
Session 5 (week 3) – Self as context	◆ Chapter 5 – Self as context ◆ Instructions about what is self as context (being the observer of your thoughts and not your thought) are explained through journal. ◆ The world starts to fall apart and becomes abstract, like a chess board. The player realises that they are the white pieces on the chessboard (analogous to chess board metaphor). ◆ The player is compelled by the game to beat the black pieces in the chess game. But the more the players fights against the black pieces, the more they lose points on the 'psychoflexameter' and cannot progress in the game. ◆ The player must let the battle paly out, once they do, they become aware that they are the chess board (they become it) and realise they do not need to be part of the never-ending battle between the opposing forces. ◆ Finally, a bus arrives, memories of the character's wife beg the player to stay, and the monsters pull on player. ◆ The player needs to get onto the bus with the monsters to move towards their values, a new beginning (analogues to bus metaphor).

- Finally, the player has a choice, go back, and change the events that led to your wife's death, or stay on the bus with the monsters. Trying to change events leads to a loss in points and prevents game progression. Only staying on the bus, towards values, and accepting the monsters allows the player to complete the game successfully.
- Reflecting in the journal about how this might be applied in life, and when this has occurred throughout the week daily.

Table 2
Qualitative interview protocol for the focus groups.

Acceptability and feasibility	How would you describe your experience of taking part in 'ACTing mind' videogame program?
Accessibility of intervention	If this intervention were rolled out as a videogame app, do you think you would download it? Would you appreciate the accessibility?
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 within the game (or applied to your everyday life)?
Suggestions for further improvement	What did you least like about the intervention? What do you think could be improved?
Barriers	Were there any difficulties to taking part?
Implementing change in everday life	Do you practice mindfulness, acceptance, defusion, and values? How often? Could you apply what you have learned through videogame 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 'ACTing Mind'? 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? Was any of it too abstarct or difficult to unbderstand?
Processes of the trial	Was there anything you liked, or disliked about the study? How could we improve this study? 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? Where than any adverse effects that you can recognise due to the intervention?

28x28mm (300 x 300 DPI)

28x28mm (300 x 300 DPI)

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	8-9	
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	8-9	
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Table 1	
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	12-17, Table 1	
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	9	
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	12	
	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	12	

	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	_____13, Table 1	_____
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	_____19____	_____
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	_____19____	_____
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_15 (but only to assess adherence and not alter it as this is a feasibility protocol)___	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_N/A (this is a protocol)_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement.** When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).