Developing and Evaluating a Stepped Change Whole-University approach for Student Wellbeing and Mental Health: trial of unguided versus guided internet CBT for acute depression and anxiety in students (Internet CBT)

Trial Protocol Version 2.0 dated 05/06/2023

This protocol has regard for the HRA guidance and order of content

Funded by: UKRI – MRC Adolescence, Developing mind and Mental Health scheme

RESEARCH REFERENCE NUMBERS

IRAS Number: Not applicable

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Sponsor protocol number: 2022-23-28

Table 1

PROTOCOL VERSION NUMBER AND DATE

Version	Date	Changes from previous version
0.1	11/1/2022	Based on HRA template as advised by sponsor
0.2	18/7/2022	Review and update by PI
0.3	01/08/2022	Review and update by PI
0.4	10/8/2022	Review by statistician
0.5	15/8/2022	Update by PI in light of DPO feedback
0.6	17/8/2022	Coding for new measures added
0.7	2/9/2022	Correction and explanation for credibility scale added
0.8	28/9/2022	Additional screening messages added; honorarium updated
0.9	11/11/2022	Further corrections and edits to remove redundancy; Amendments as agreed at TSC meeting
1.0	04/01/2023	Amendments as agreed at TSC meeting
1.1	24/4/2023	Amendments confirmed by PI
2.0	05.06.2023	Key contacts update. Removal of committee member names. Addition of TikTok as a social media advertising avenue. Section 7.1.3 payment amounts clarified. Section 7.4 clarification of who is blinded and unblinded. Section 9 Adverse event reporting requirements changed in line with Exeter Clinical Trials Unit SOP and AE and SAE examples updated. SAE reporting flowchart updated. Section 10.2 Revised recruitment end date specified. Minor revisions, typing errors, layout and formatting updated throughout. GP letters removed and stand-alone documents created. SAE form removed as out of date (revised version available electronically on database).

Table 2

PROTOCOL AMENDMENTS

Amendment	Date	Changes from previous version	Date Authorised
Non-substantial amendment 1 (CTU)	**05.06.2023**	**Key contacts update. Removal of committee member names. Addition of TikTok as a social media advertising avenue. Section 7.1.3 payment amounts clarified. Section 7.4 clarification of who**	**13.07.2023**

V3.0 Amendment (REC)		**is blinded and unblinded. Section 9 Adverse event reporting requirements changed in line with Exeter Clinical Trials Unit SOP and AE and SAE examples updated. SAE reporting flowchart updated. Section 10.2 Revised recruitment end date specified. Minor revisions, typing errors, layout and formatting updated throughout. GP letters removed and stand-alone documents created. SAE form removed as out of date (revised version available electronically on database).**	

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol and will adhere to the principles outlined including clinical trial regulations, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the trial will be given; and that any discrepancies and serious breaches of GCP from the trial as planned in this protocol will be explained.

For and on behalf of the Trial Sponsor:

Signature: Date:

Name (please print): Ms Pam Baxter

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Position: Senior Research Governance Officer

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Chief Investigator:

Signature:  Date: 05.06.2023

Name (please print):

Edward Watkins.....

KEY TRIAL CONTACTS

Table 3 Key contacts

Chief Investigator	Professor Ed Watkins, Sir Henry Wellcome Building for Mood Disorders Research, School of Psychology, College of Life and Environmental Sciences, University of Exeter, EX4 4QG. 01392 724692, e.r.watkins@exeter.ac.uk
Project Administrator	Nicole Madeley, Sir Henry Wellcome Building for Mood Disorders Research, School of Psychology, College of Life and Environmental Sciences, University of Exeter, EX4 4QG.
Trial manager	Dawn Phillips, Exeter Clinical Trials Unit, College of Medicine and Health, University of Exeter, College House, St Luke's Campus, Magdalen Road, Exeter, Devon, EX1 2LU d.phillips4@exeter.ac.uk
Sponsor	University of Exeter Sponsor's Representative Ms Pam Baxter Senior Research Governance Officer University of Exeter, Research Ethics and Governance Office, Lafrowda House St Germans Road, Exeter, Devon EX4 6TL Email: p.r.baxter2@exeter.ac.uk Tel: 01392 723588 Mobile: 07485042117
Funder(s)	UKRI Medical Research Council
Clinical Trials Unit	Lynne Quinn/Siobhan Creanor, Exeter Clinical Trials Unit, College of Medicine and Health, University of Exeter, College House, St Luke's Campus, Magdalen Road, Exeter, Devon, EX1 2LU, 01392 726 037 https://ctu.exeter.ac.uk
Key Protocol Contributors	Professor Ed Watkins, Professor Gordon Taylor
Statistician	Professor Gordon Taylor, College of Medicine and Health, University of Exeter, College House, St Luke's Campus, Magdalen Road, Exeter, Devon, EX1 2LU, 01392 726 037 Dr James Connors, Institute of Health Research, University of Exeter, Devon, j.connors@exeter.ac.uk
Site Team	University of Exeter (Trial Manager, project administrator and chief investigator (contacts above)
Other sites: recruitment only	University of Oxford, King's College London, University of Newcastle, Southampton University, Cardiff University

CONTENTS LIST

i. LIST OF ABBREVIATIONS

Define all unusual or 'technical' terms related to the trial. Add or delete as appropriate to your trial. Maintain alphabetical order for ease of reference.

AE	Adverse Event
AR	Adverse Reaction
CA	Competent Authority
CI	Chief Investigator
CRF	Case Report Form
CRO	Contract Research Organisation
CTA	Clinical Trial Authorisation
CTIMP	Clinical Trial of Investigational Medicinal Product
CTU	Clinical Trials Unit
DMC	Data Monitoring Committee
DMEC	Data Management and Ethics Committee
DMP	Data Management Plan
DoW	Description of Work (Annex 1 of the Grant Agreement)
DSUR	Development Safety Update Report
EAB	External Advisory Board
EC	Emotional Competence
ECom	European Commission
eCRF	Electronic Case Report Form
EU	European Union
EUCTD	European Clinical Trials Directive
EudraCT	European Clinical Trials Database
GA	General Assembly
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
IB	Investigator Brochure
ICF	Informed Consent Form

IMB	Innovation Management Board
IP(R)	Intellectual Property (Rights)
ISF	Investigator Site File (This forms part of the TMF)
ISRCTN	International Standard Randomised Controlled Trials Number
ITR	Individualised Treatment Rules
MA	Marketing Authorisation
MS	Member State
PI	Principal Investigator
PIC	Participant Identification Centre
PIS	Participant Information Sheet
PMT	Project Management Team
QA	Quality Assurance
QC	Quality Control
QP	Qualified Person
RCT	Randomised Controlled Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
SC	Steering Committee
SDV	Source Data Verification
SOP	Standard Operating Procedure
SSI	Site Specific Information
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
TMG	Trial Management Group
TP	Trial Protocol
TSC	Trial Steering Committee

WP(L)	Work Package (Lead)
YAB	Youth Advisory Board

Location/Collaborator Abbreviations

EXCTU	Exeter University Clinical Trials Unit
UNEXE	University of Exeter
UCARD	University of Cardiff
UOXF	University of Oxford
UNEW	University of Newcastle
KCL	King’s College London
USOTON	University of Southampton

ii Project Summary

Our overall project aim is to develop and evaluate an acceptable, effective, cohesive system of whole-university and stepped care student wellbeing and mental health support. Our main objective is to resolve uncertainties as to which elements and steps within this approach are most acceptable and effective for promoting good mental health in university students, how they interact, and which work best for whom. We will derive an evidence-based model of integrated approaches to inform best practice and policy recommendations for delivering inclusive, effective, sustainable, scalable student wellbeing mental health support.

Key cross-cutting objectives include to:
(1) Examine acceptability, uptake, adherence, effectiveness across different initiatives at different levels of stepped support (at Step 1 compassionate education; online mental health literacy (MHL); digital self-monitoring; at Step 2 guided, unguided self-help; at Step 3 digital self-monitoring in mental health services).
(a) Evaluate whether building compassion into university culture, organisation and coursework is feasible and improves wellbeing, academic outcomes and inclusivity across diverse groups.
(b) Assess whether a digital self-monitoring tool improves emotional self-awareness, wellbeing, and access to appropriate support.
(c) Assess whether an online MHL course is engaging, increases mental health knowledge, healthy behaviours, access to support and reduces stigma.
(d) Test whether unguided digital rumination-focused self-help intervention prevents depression in high-worry students.
(e) Compare the efficacy and acceptability of different digital self-help and book-based self-help for students with elevated anxiety and depression.
(f) Evaluate whether adding a digital self-monitoring tool to routine student mental health services improves student engagement, care management and outcomes.

(2) Map the student journey along the stepped pathway to identify barriers, facilitators and gaps and to understand what events, symptoms and mechanisms influence student transitions between initiatives.

(3) Understand how student wellbeing and mental health needs vary across diverse groups (e.g. gender, sexuality, socioeconomic background, ethnicity, prior mental health history) over time and barriers and facilitators to accessing support for these diverse groups.
(a) Create a large representative longitudinal dataset (n>5000) of students across diverse groups and universities, with biannual assessment of wellbeing, mental health, process mechanisms, preferences, knowledge and behaviour re mental
health and access to support services.

(b) Assess the ongoing impact of COVID-19 and its consequences (social distancing, blended educational approaches) on student wellbeing.
(4) Better understand heterogeneity of intervention effects for students.
(a) Explore which subgroups of students with elevated anxiety and depression are particularly responsive to unguided digital interventions.
(b) Identify predictors of who benefits from different digital interventions.
(c) Produce exploratory Individualised Treatment Rules (ITRs) to guide the selection of treatments most likely to be helpful for students.

(5) Identify which hypothesized mechanisms for the promotion of good mental health are most associated with positive outcomes to guide which active components to enhance and include in stepped care model. Test the extent to which increasing (a) emotional self-awareness; (b) self-compassion; (c) mental health knowledge; (d) sense of belonging; (e) use of helpful cognitions and behaviours mediate positive outcomes across all initiatives.

(6) Develop and refine existing initiatives in partnership with students with co-creation workshops for digital self-monitoring tool, online MHL, strengths-based guided self-help.

(7) Develop a rich understanding of students' perspective and experience of stepped care through qualitative analysis of student focus groups and interviews.

Our research involves a rigorous evaluation of whole-university and stepped care frameworks to promote good mental health in students using a multi-disciplinary approach drawing on the humanities, psychology, psychiatry, information technology and statistics, working collaboratively across 6 universities.

To address objective 1, we will introduce different whole-university (embedding compassion in education; online mental health literacy course) and stepped care interventions (digital self-monitoring) in a phased way across collaborating universities.

To address objectives 2,3,5, a repeated biannual online student wellbeing survey at the start and end of the academic year, with cross-sectional and longitudinal components, will collect self-report quantitative data (demographics, mental health outcomes, process measures, attitudes, knowledge of and behaviours related to stepped care) from students across multiple institutions. Students can use a digital self-monitoring tool and electronic personal health record prospectively, with brief measures of wellbeing, stress, symptoms and use of support to address objective 2. We will test whether this tool helps students to better use stepped care. Observational experiments will collect pre- and post-intervention quantitative and qualitative

data using a core set of outcome measures and examine data from biannual surveys to assess the impact of introducing each intervention.

To address objectives 6, 7, focus groups will explore students' experiences of these initiatives including positives, negatives, areas to improve and relevance to diverse groups.

To address objectives 1,4,5, randomised trials will compare different variants of digital self-help including guided vs unguided self-help.

To address objective 4, pre-randomisation measures will assess potential predictors of heterogeneity of treatment effect. Repeated weekly web surveys within the trials will assess change in putative mediators to support objective 5.

This specific trial of guided vs unguided CBT to treat current anxiety and depression will specifically test objective 1 (e) and 4 (a), (b), (c).

The trial tests the following hypotheses:

(1) On average, guided internet CBT for anxiety and depression will outperform unguided self-help internet CBT for anxiety and depression in reducing symptoms of depression and anxiety;

(2) (a) There will be a subset of individuals /students for whom unguided self-help internet CBT is as effective as guided internet CBT in reducing symptoms of anxiety and depression:

(b) Individualised treatment rules can be derived to predict who will benefit optimally from either guided versus unguided internet CBT and for whom the interventions will be of equivalent efficacy

Table 4 Summary of Study

Trial Title	**Developing and Evaluating a Stepped Change Whole-University approach for Student Wellbeing and Mental Health: Nurture-U trial of unguided versus guided internet CBT to treat acute depression and anxiety in students**	
Internal ref. no. (or short title)	**Nurture-U Internet-based cognitive-behavioural therapy for anxiety and depression in UK university students (Internet CBT)**	
Clinical Phase	III	
Trial Design	Phase III superiority parallel 2-arm randomised multicentre, randomized controlled trial (RCT)	
Trial Participants	UK university students with elevated symptoms of depression (PHQ-9 > 9) and/or anxiety (GAD-7 > 9).	
Planned Sample Size	720 for overall cohort.	
Treatment duration	Unguided versus guided CBT digital intervention, typically completed over 6-12 weeks	
Follow up duration	Over three months The primary time point is 3 months	
Planned Trial Period	32 months (starting recruitment to final follow up)	
	RCTs & measures	**Outcome domains**
Primary outcome	Depression PHQ9 Anxiety GAD-7	Indices of anxiety and depression as joint primary outcome
Secondary outcomes	Functioning – WSAS Wellbeing – WEMWBS (7-item) Brooding Worry (PSWQ-Short) Use of services/treatment – Academic outcomes - self-report	indices of poor mental health and wellbeing

	Stress Resilience	
Mediators	rumination, habit change, self-compassion, behavioural coping skills	
Intervention	Two intervention group: Unguided transdiagnostic online CBT for anxiety and depression (i.e., without any therapist support). Guided transdiagnostic online CBT for anxiety and depression – i.e., with therapist support from psychological wellbeing practitioner – typically online, asymmetric support	
Route of Administration	Online access via smartphone, web, computer	
Hypotheses	(1) On average, guided internet CBT for anxiety and depression will outperform unguided self-help internet CBT for anxiety and depression in reducing symptoms of depression and anxiety; (2) (a) There will be a subset of individuals /students for whom unguided self-help internet CBT is as effective as guided internet CBT in reducing symptoms of anxiety and depression: (b) Individualised treatment rules can be derived to predict who will benefit optimally from either guided versus unguided internet CBT and for whom the interventions will be of equivalent efficacy	

iii.Funding and support

Table 5 Funding and Support in Kind

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
UKRI MRC	£3780,000

iv. Role of Trial Sponsor and Funder

Role of Funder

The research funder has the responsibility to ensure that there is a proper use of the funds they control. The study is funded by the UKRI/MRC. The Funder has conducted a review of the study, provided feedback to the consortium, and has established that the research is worthwhile, of high scientific quality and represents good value for money. The research funder has assessed the experience and expertise of the Chief Investigator, other key researchers on the programme and has deemed that there is appropriate infrastructure for the research to be carried out.

The funder plays no further role in the design of this individual study and will have no role in data analysis or interpretation or writing up of findings of the study. The funder will be sent all outputs prior to dissemination but has no role in the decision to submit for publication.

Role of Sponsor

The study sponsor will ensure that the research team has access to resources and support to deliver the research as proposed and that responsibilities for management, monitoring and reporting of the research are in place prior to the study commencing. The sponsor will ensure that there is agreement on recording, reporting, and reviewing significant developments as the research proceeds and approve any modifications to design, obtaining requisite regulatory authority.

The sponsor will assume responsibility for operating the management and monitoring systems of the research. Prior to the study commencing the sponsor will be satisfied that:

- The research will respect the dignity, rights, safety and well-being of participants and the relationship with healthcare professionals.
- The research will be reviewed and approved by the appropriate Research Ethics Committee.

- The Chief Investigator, and other key researchers have the requisite expertise and have access needed to conduct the research successfully.
- The arrangements and resources proposed for the research will allow the collection of high quality, accurate data and the systems and resources will allow appropriate data analysis and data protection.
- Organisations and individuals involved in the research agree the division of responsibilities between them.
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments during the study, whether in relation to the safety of individuals or scientific direction.
- There are arrangements for the conclusion of the study including appropriate plans for the dissemination of findings.

The sponsor plays no role in the design of this study and will have no role in data analysis or interpretation, or writing up of findings of the study.

v. Roles and Responsibilities of Trial Management Committees/Groups & Individuals

There are a number of workstreams within the overall University Mental Health project – the relevant workstream for this trial is Workstream 4 (WS#4): Guided and unguided self-help cognitive-behavioural therapy (CBT) for student wellbeing and MH (leads Watkins, Farrand;+Gallop, Robinson, Taylor).

This trial protocol document focuses on governance and structure related to the conduct of the trial only.

The University of Exeter will act as the sponsor for the study; the study will be hosted in the Mood Disorders Centre and the Exeter Clinical Trials Unit, which has experience in the successful delivery of internet and prevention trials.

The Trial Management Group

The Trial management group will oversee and manage the randomised controlled trials and consists of the chief investigator, the project manager, the study manager, the statisticians, the data team and representatives from the EXCTU management team. A subset of the group will meet fortnightly, with a monthly meeting to review progress and milestones.

Table 6 Members of the Trial Management Group

Member type	Institution	Contact details
Trial manager	EXCTU	Teamnurture-U@exeter.ac.uk
Lead Statistician(s)	EXCTU	
IT support	EXCTU	

Ed Watkins Chief Investigator (CI)	UNEXE	e.r.watkins@exeter.ac.uk
Senior trial manager/trial manager lead	EXCTU	
Project administrator	UNEXE	
Data management & IT	EXCTU	

The Nurture-U CBT acute treatment Trial Steering Committee (TSC)

The TSC will be chaired by an independent chair, with relevant clinical and academic experience and will also include current members of our Student Advisory Board with representatives from specialist mental health professionals. The TSC will meet at the beginning of the trial and it is proposed that it meets every 6 months thereafter to oversee its conduct. It will include the trial PI, trial manager, trial statistician plus at least 3 independent members, where possible, members of the independent Expert Advisory Board. The Trial Steering Committee (TSC) will have a monitoring and decision-making role for the trial, including recruitment, progress, and other milestones. The TSC will report to the funder and trial sponsor and has the authority to recommend the suspension or discontinuation of the trial to the sponsor. Minutes of the meeting will be prepared by the Chair (or delegate) and circulated for agreement by the full membership over e-mail within a reasonable time following the meeting. All members of the TSC will contribute to discussion and decisions but to ensure that in decision making >50% of the membership is independent, co-investigators and collaborators will not have voting rights.

TSC Terms of Reference

1. To monitor recruitment and supervise the progress of the trial towards its objectives;
2. To consider recommendations of the relevant Research Ethics Committee;
3. To inform the funders (UKRI/MRC) on the progress of the trial;
4. To advise funders and trial Study Management Group on publicity and the presentation of all aspects of the trial;
5. In the event of further funding being required, to provide to the funders appropriate information and advice on the data gathered to date without jeopardising the study;
6. To ensure appropriate oversight of, and involvement in, trial management from lay advisers who have relevant lived experience.

Trial Data Monitoring and Ethics Committee (DMEC)

An independent DMEC will consist of at least an independent statistician/methodologist and at least two independent clinician/researcher members, (with the Chair of the committee coming from one of the methodologist or clinician). The DMEC will meet every 6 months and if necessary, in response to any serious untoward incidents. The DMEC will review adverse events and monitor data with access to group allocation with respect to recruitment, retention, and safety, and report to the TSC. The DMEC will be responsible for monitoring serious adverse effects, protocol violations and any risks emerging from the trial. It has the capacity to conduct an unblinded analysis if concerned about serious adverse effects.

Terms of Reference

The Terms of Reference for the DMEC can be found here:

1. To determine if interim analyses of trial data should be undertaken
2. To consider the data from interim analyses (un-blinded if appropriate)
3. Consider any safety issues for the trial and recommend appropriate contingencies
4. To consider any requests for release of interim trial data
5. To monitor data, risk, and adverse outcomes in the trial

University Mental Health External Advisory Board (EAB)

The role of the EAB is to periodically review the progress and results of the overall project from a variety of angles and provide advice on ongoing and future work. The EAB will be composed of internationally renowned scientists, representatives for student mental health and stakeholders involved in the delivery of mental health and wellbeing support within higher education including clinical professionals, students, policymakers and senior management. Specifically, the EAB will provide independent advice on (i) managing the project and maximising its scientific, technological and health-related impact; (ii) the exploitation of the most promising results and planning and supporting future implementation and impact The EAB shall also assist and facilitate the strategic decisions made by the project steering group and provide tactical recommendations on management, impact or methodology to the Steering group. The chair and membership of the EAB will set their terms of reference in liaison with the Project Management Team. The EAB will meet at least annually either in person or via videoconference.

vi. Protocol contributors

This protocol has been written by the chief investigator and lead PI for the trial Professor Ed Watkins and trial manager with the assistance of Lynne Quinn (Operations Manager) from the University of Exeter Clinical Trials Unit. Tim Eames have contributed to the data management sections and Professor Gordon Taylor (Exeter CTU member) and Dr James Connors (trial statistician) to the statistical analysis sections.

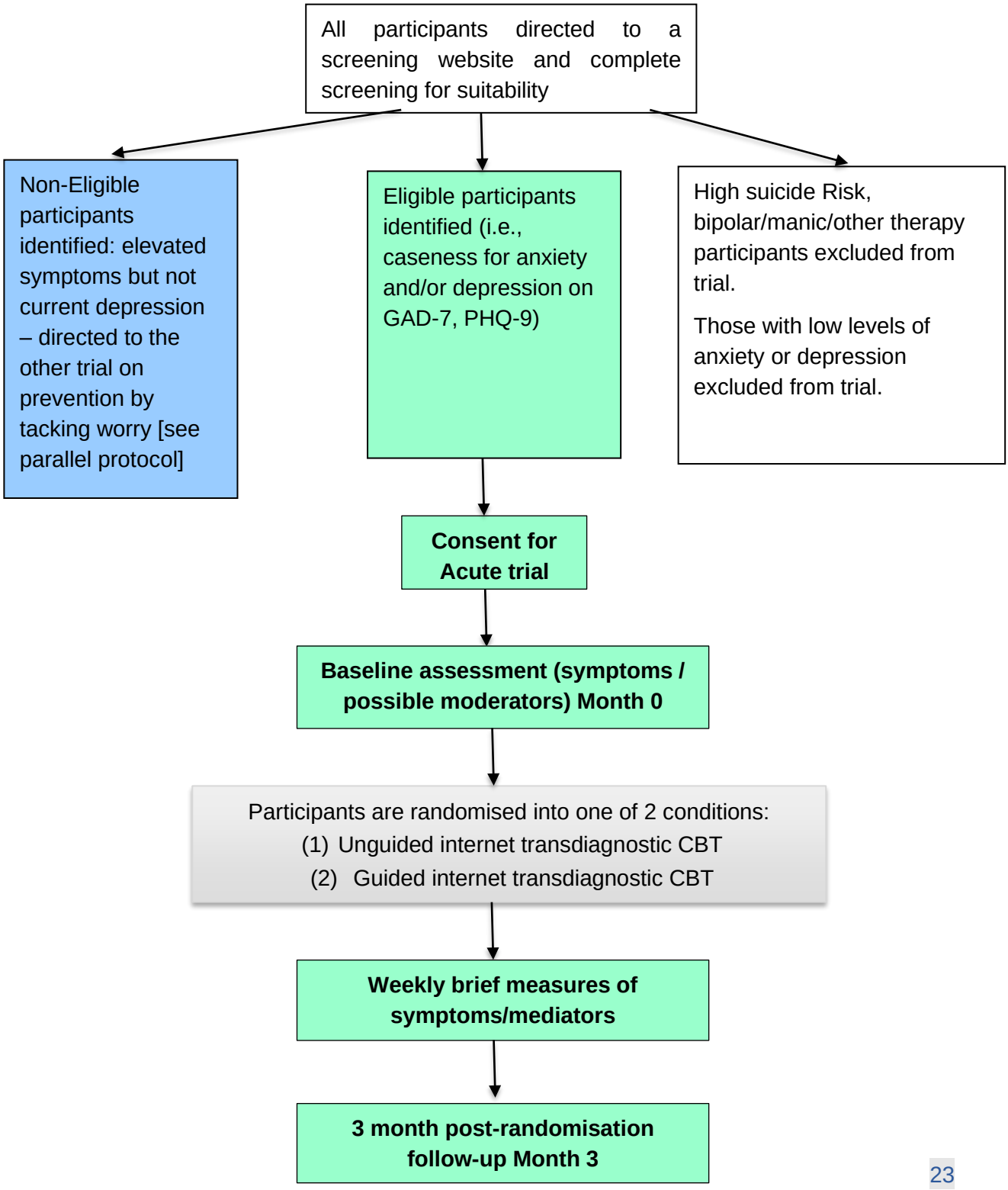
vii. KEY WORDS:

treatment, internet delivery, CBT, guided versus unguided, depression, anxiety, transdiagnostic, personalised individualised treatment rules, machine learning

viii. TRIAL FLOW CHART

Figure 1 Illustration of randomised controlled trial for unguided vs guided internet CBT for acute anxiety and depression

Large observational cohort of young adults recruited (n= 720)



1 BACKGROUND

University provides an opportunity for young people to develop independence, positive self-identity, good coping skills and social-emotional resources to stand them in good stead through their lives, as they face challenges like leaving home, meeting academic standards, making new friends, managing finances. However, university is also a high-risk period for stress and poor mental health (MH), which can result in increased drop-out, poorer academic outcomes, diminished employment opportunities and long-term disadvantage[1-3]. MH concerns are increasing amongst university students, with anxiety, depression, self-harm and alcohol/substance abuse most common [4-8]. These MH concerns are likely to increase further because of the COVID-19 pandemic [9] and resulting uncertainties, loneliness, and restrictions. Therefore, improving student wellbeing and promoting good MH provides a key window of opportunity to promote flourishing and generate long term benefit for our students and wider society.

Our vision is for all higher education students to have ready access to inclusive, effective, integrated, and tailored wellbeing promotion and MH support developed in partnership with students. This vision meets the call's remit by addressing several inter-related challenge areas: prevention and intervention; inter-individual heterogeneity focused on who may be more likely to engage and respond to different initiatives and addressing the needs of diverse student groups including potentially vulnerable subgroups; societal transformation focused on the impact of COVID-19; examining the education environment to explore how university environments can foster wellbeing.

Our aim is to bring together expertise and initiatives from different institutions to develop and evaluate a cohesive, scalable and sustainable system of whole-university and stepped student wellbeing and MH support.

Key objectives include to: (a) examine acceptability, uptake, adherence, and effectiveness across different initiatives at different levels of stepped support; (b) map the student journey along the stepped pathway to identify barriers, facilitators, and gaps and how different steps and initiatives interact; (c) derive an evidence-based model of integrated approaches to inform best practice for effective and sustainable delivery of inclusive university MH and wellbeing support.

Across these objectives, a key issue is understanding how MH needs vary across diverse groups (by gender, sexuality, socioeconomic background, ethnicity, MH history, international students, carer status) and what different support elements are more likely to engage and help individuals from these diverse groups. We will explore which approaches work best for which individuals or subgroups.

2 RATIONALE

University MH services report a dramatic increase in the number of students seeking help for MH concerns and a growing disparity between student demand and current resources

[8,10,11]. Since most students with MH problems access services via their university rather than the NHS, there is now a major treatment gap. The organization, provision and means for students to access MH services varies across institutions. None of the different models of services [8,11] nor most student MH initiatives have been systematically evaluated and are often applied without a direct evidence base. Major challenges for enhancing student MH include: (Challenge 1: C1) incomplete mapping of the scope and complexity of MH need, especially with respect to inclusivity and diversity11; (C2) absence of proven effective prevention and wellbeing promotion initiatives[12,13]; (C3) a need to improve student engagement: most students experiencing poor MH do not seek formal support from university or NHS services[8]; (C4) long wait-times for counselling and therapy support [11]; (C5) a lack of integrated support planning and proactive follow-up; (C6) traditional face-to-face interventions alone lack sufficient capacity to address the full spectrum of need; (C7) community MH services do not align well with student need given peripatetic nature of student life, with poor continuity of care between University and NHS services.

Despite increasing research into student MH, there remain sizeable knowledge gaps as to the prevalence and drivers of MH problems in UK university students, with respect to which approaches work and are acceptable to students, including for diverse and minority groups (e.g., BAME, LGBTQ+, international, MH history, socioeconomic background) and critically, as to what overarching model of organized MH support for students works best. The recent University Mental Health Charter[14], a product of research synthesis, stakeholder consultation, and student co-creation recommended a systemic whole-university approach to MH, arguing that institutional environment, organisational culture, course content and delivery are important for MH, along with the integration of promotion and prevention and the provision of specialist support (see also[8]). In parallel, recent reports[11] and the Universities UK StepChange framework[15] recommended stepped care tailored to the university environment to address the capacity and complexity of MH support needs. Stepped care typically involves access to and movement between different levels of intensity based on need, ranging from predominantly community-led prevention and promotion approaches for individuals without symptoms (Step 1) to low-intensity self-help interventions for individuals with mild-to-moderate symptoms (Step 2) to psychotherapy or counselling for those with elevated symptoms (Step 3). However, to date, neither the whole-university nor the stepped change approach have been systematically evaluated within and/or across universities.

Our programme therefore advances the field by providing the first attempt to systematically investigate a coherent model of MH promotion and support for the diverse university student population. We will address major support gaps and key knowledge gaps by investigating multiple initiatives all coordinated within a systemic whole-university and stepped change framework to promote student wellbeing and good MH. We will reduce uncertainty in the evidence base and tackle the challenges identified above through diverse methodologies including focus groups, pilot studies to assess feasibility and adherence, and

proof-of-concept randomised controlled trials (RCTs). Our programme is novel and provides added translational value and value for money by investigating and integrating complementary initiatives (each a specific workstream) at each level along a stepped change pathway and their interactions: at Step 1 compassionate education, MH literacy; at Step 2 guided vs unguided self-help; at Step 3 enhanced care for students experiencing common MH conditions. To inform the scope and trends in student MH need and evaluate transitions through the stepped initiatives, a cross-cutting workstream uses (a) repeated electronic student wellbeing surveys; (b) a digital self-monitoring tool, which may itself improve access to support and promote integrated support planning. Each initiative will be embedded in existing structures or practice (e.g., teaching, wellbeing services) or use proven and available digital interventions to make the research cost-effective and support sustainable implementation beyond the grant. Through five intercoordinated workstreams, our integrative central research question is: What combination(s) of approaches within this framework is/are most acceptable and effective at promoting good student MH, for whom, and how do these different steps interact? Crosscutting research questions across all workstreams ask for each initiative: Can it be feasibly implemented? What is the uptake and experience among students from diverse backgrounds? What is its effect on wellbeing, symptoms, academic performance? How does it influence students accessing other parts of the stepped support framework? What are the mechanisms-of-action?

CONCEPT AND METHODOLOGY

Overall Concept: **Guided and unguided self-help cognitive-behavioural therapy (CBT) for student wellbeing and MH (leads Watkins, Farrand;+Gallop, Robinson, Taylor).**

Low-intensity (LI) self-help CBT, with or without support from a MH professional (e.g., a psychological wellbeing practitioner, PWP), delivered via books or digitally (at Step 2) is proven effective for treating common MH difficulties[30-32], improves access and reduces delivery costs (e.g., NHS IAPT programme). Further, digital self-help is highly scalable and usable anywhere, anytime, potentially addressing treatment barriers and challenges C4, C6, C7 around treatment access, capacity, convenience, and availability. Digital CBT for mild-to-moderate anxiety and depression is efficacious in students [33]. Students generally view online interventions positively [34]. Despite this, self-help CBT has been less frequently incorporated and evaluated within university student MH support services and when used does not always adhere to established LI-CBT precepts and is not typically adapted for students.

A key uncertainty within digital self-help is heterogeneity of treatment effects (HTE) i.e., variations in individual treatment response to particular treatments[33,35]: understanding which digital self-help interventions are most acceptable and work best for which students could help

to tailor self-help interventions, plan the care pathway, and improve outcomes. A critical question is how much and what kind of support from a practitioner is needed: unguided self-help has greater reach, sustainability and scalability as it is not limited by therapist capacity, opening up the potential for massive cost-effective open online interventions[36] but may have less engagement and efficacy than guided interventions[35,37,38], although there is heterogeneity[33,35], with a subset of individuals helped as much by unguided self-help as guided self-help[38,39]. Identifying such a subset would be of enormous value in increasing treatment scalability, tackling C4, C6.

Third, the mechanisms-of-action of these self-help CBT interventions remain unresolved. Hypothesized mechanisms include (a) improved emotional self-awareness; (b) increased self-efficacy; (c) learning new cognitive and behavioural coping skills and (d) social support (for guided treatment). Delineating mechanistic insights enables individual interventions to be further enhanced and the stepped care model to be planned to target all active mechanisms.

This trial is focused on the following questions:

1. Which digital interventions are acceptable to which students and do they reduce symptoms and demand for other services?

2. What subsets of students are particularly responsive to unguided digital interventions?

METHODS OVERVIEW:

To address these questions, investigate which digital self-help is most acceptable and helpful for students with anxiety and depression, and explore predictors of HTE, a proof-of-concept parallel arm individual-level single-blind superiority RCT will randomize 720 students with elevated depression (PHQ-9>9) and/or anxiety (GAD-7>9) across two widely used transdiagnostic digital interventions (there is no upper limit for PHQ-9 or GAD-7 re entry criterion for the study). The proposed interventions are chosen to have an existing evidence-base (albeit not necessarily in students) and differ sufficiently enough to enable investigation of relative student engagement and HTE particularly with respect to the effects of guided vs unguided self-help and to answer RQ10: and to test different mechanisms-of-action: unguided versus guided versions of online CBT self-help[46]. Students will be recruited across all partner universities.

[This is revised from the original design in the grant (that had 4 arms including mindfulness app and peer support app) for the following reasons. Expert colleagues recommended as a minimum that we take the original 516 participants and split it 2 ways rather than 4 ways to increase our power to derive models to personalise students to one or other of the 2 students.

If we follow the guidance from recent work on developing these models, it is worth trying to add c.200 participants to further increase our ability to generate these models robustly, which we believe is feasible to recruit in the time-scale.

The rationale for the proposed change is as follows:

(a) The primary question for this trial is what subsets of students are particularly responsive to unguided digital interventions and by focusing on the guided and unguided digital CBT, we will increase the power to properly answer this question in a UK context – i.e., increase the likelihood of sample size being sufficiently large for the predictive modelling to generate robust individualised treatment rules. Several external researchers have strongly encouraged us to do this.

(b) This comparison of guided vs unguided digital CBT is the most useful from a service delivery and cost-effectiveness perspective as it is the one with greatest implications for university wellbeing services implementation. Such packages (e.g., Silvercloud – Space from Anxiety, Space from Depression) are routinely being offered by universities, typically in an unguided format, at a license cost to the university but without knowing if they are being offered to the right students or if supported versions would do better if targeted appropriately. In contrast, the apps mentioned are typically free-to-access and students may use independently of services, so there are fewer implications for service delivery of knowing which works for whom. There is also not a contrast between a guided and unguided version which is where staffing and cost implications and the value of directing students to the most appropriate early comes in.

(c) It has become clearer that the American and other international projects where we intended to pool data to further increase power only have the comparison of guided vs unguided digital self-help as the common element, so the other arms if retained would likely to be underpowered for generating ITRs.

(d) With further research amongst our experts and stakeholders, it has been hard to find a satisfactory peer support platform, with appropriate monitoring, risk management and data protection.

(e) We will still address the question re which digital interventions are acceptable to students and which reduce symptoms through the combination of this trial and the work on the digital self-monitoring tool in WorkStream #1. As the project is emerging that self-monitoring tool looks like a better means to offer /signpost students to relevant free-to-access apps e.g., for mindfulness, to see if they are taken up (i.e., testing acceptability), to get feedback on them, and to assess symptoms over time. This reasoning was accepted and signed off by Prof Eamonn McCrory on behalf of the funder UKRI].

Primary outcome will be self-reported depression (PHQ-9) and self-reported anxiety (GAD-7) assessed 3 months after randomization. Adherence, academic outcomes, use of support services (WS#1; WS#5) will be secondary outcomes. This will include measures of the use of the digital intervention (including number of modules completed, time taken to complete for both guided and unguided variants).

To examine potential predictors of HTE and identify who may most benefit from which digital interventions, we will use a self-report web-based assessment pre-randomization. Measures will be those that predicted treatment outcome in prior studies: demographics, diversity, MH history, symptoms (from WS#1 core set) plus stress, personality.

We hypothesize that whilst guided self-help will on average be more efficacious than unguided self-help, for a subset of users there will be no difference in effectiveness. We aim to identify the profiles of those students who would benefit most from unguided self-help relative to guided self-help and those that need to be directed to guided interventions.

As an exploratory first step, we will test which pre-treatment measures moderate the differential effects of treatment condition. Because individual predictors are usually weak and underpowered, an improved approach is to use composite models that combine individual moderators to produce Individualised Treatment Rules (ITRs) that can guide the selection of treatments most likely to be helpful for individual students. We plan to work with collaborators in WMH-ICS network, led by Prof Ron Kessler, Harvard, with expertise in machine learning and analytics to use SuperLearner ensemble machine learning method to develop pilot ITRs [48,49].

The Super Learner model uses 10-fold cross-validation to select a combination of weights across an ensemble of candidate classifier algorithms to combine differences in predicted probabilities of treatment success in such a way as to guarantee optimal prediction of the relative effectiveness of alternative interventions. This approach has been validated as a means to develop effective composite models, e.g., developing preliminary ITR with n=150[48].

This RCT is designed to be compatible with an ongoing RCT of digital apps for student MH (target >2000 students) enabling data pooling for sufficient statistical power to investigate HTE, given that n=300 patients per arm is sufficient to provide stable estimates of ITRs[50]. Identifying ITRs is a key step towards precision treatment personalisation and to prepare for definitive trials that test whether treatment allocation using ITRs improves outcomes relative to random allocation or usual practice.

To investigate putative mediators and test hypotheses about mechanisms (e.g., unguided

CBT hypothesized to work via learning new cognitive and behavioural coping skills; guided CBT hypothesized to involve both learning coping skills and support;), eight weekly 5-minute web surveys will be used during the intervention period to monitor relevant brief process measures, treatment engagement, anxiety, and depression.

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

Trial Objectives

To evaluate the effectiveness of an unguided internet-delivered transdiagnostic CBT intervention package for acute depression and anxiety in students relative to the same transdiagnostic package with guidance from a therapist (Psychological Wellbeing Practitioner). The intervention has the potential to be scalable, easily available, low cost, convenient, acceptable, and to tackle equality of access (see also Kazdin, 2015).

Furthermore, the objectives are to examine the following questions:

What subsets of students are particularly responsive to unguided digital interventions?; and to then attempt to develop individualised treatment rules (ITRs) that can suggest which intervention (guided vs unguided) is more suitable for which individual, i.e., which individuals will respond just as well to unguided i-CBT and which would particularly benefit from the guided version of i-CBT.

Outcomes will be self-reported depression and anxiety symptoms (primary outcome) as well as resilience, social functioning, and educational achievement (secondary outcomes).

3.1 Primary/secondary objectives and research hypotheses

The primary efficacy objective in the trial will be to evaluate symptomatic anxiety and depression at the 3 month follow up (*primary endpoint*) in university students who have major depression and/or anxiety disorders at baseline (as operationalized by caseness on PHQ-9 and GAD-7, i.e., scoring <= 9 on each measure. Recovery will be defined as both anxiety and depression being below the threshold for caseness (paralleling IAPT operationalization). When modelling for the heterogeneity treatment effects, there may be differences when modelling what variables/models predict improvement in depression and what predict improvement of anxiety, and thus each will need to be modelled separately.

The primary modelling objective in the trial is to develop and test potential Individualised Treatment Rules (ITRs) that can guide the selection of treatments most likely to be helpful for individual students – in particular, to identify the profiles of the subset of those students who

would benefit most from unguided self-help relative to guided self-help versus those that need to be directed to guided interventions.

The *primary outcome measures* will be PHQ-9 and GAD-7 across the 3-month follow-up. Recovery will be defined as both anxiety and depression being below the threshold for caseness (paralleling IAPT operationalization).

Hypotheses

(1) For university students with depression and/or anxiety, on average, guided transdiagnostic i-CBT will outperform unguided transdiagnostic i-CBT in

- reducing symptoms of depression at 3 (1a; co-primary outcome, as index of poor mental health; PHQ-9);
- reducing symptoms of anxiety at 3 months (2a); (co-primary outcome, as index of poor mental health; GAD-7)
- improving rates of recovery (defined as both GAD-7 <=9 and PHQ-9 <=9).
- increasing mental well-being (WEMWBS), social and occupational/academic functioning (WSAS), academic outcomes) at 3 months (2c). (secondary outcome).

(2) Whilst guided self-help will on average be more efficacious than unguided self-help, for a subset of users there will be no difference in effectiveness.

(3) This subset can be identified using machine learning to develop ITRs to predict who will benefit from guided i-CBT, unguided i-CBT or for whom the treatments are equivalent. [This will be a sub-study within the overall trial]

Secondary objectives will be: (1) to assess the effects of the intervention on primary and secondary outcomes.

Additional secondary outcome measures will assess anxiety, mental well-being, social functioning, and educational achievement (see **Table 7**).

Demographic information

Demographic information will be collected at baseline including participant age, sex, country of birth, country where currently reside, ethnic group, educational level, occupation, and parent's occupation. Occupational status of participant and their parent(s) will be used as an index of socio-economic status.

3.2 Moderator/Predictor/modelling information

A self-report web-based assessment conducted pre-randomization will collect data on measures that have predicted treatment outcome in prior studies including demographics, diversity, Mental Health history and treatment, co-morbid symptoms (from WS#1 core set) plus stress, personality and coping styles. For further details see Appendices.

This will include: Past history of depression ; perceived physical/mental health; role impairment; mental /physical health symptoms; cognitive functioning, anger/irritability; mental health history, Sleep problems; substance use; generalized anxiety, panic, obsessive-compulsive disorder, posttraumatic stress disorder, suicidal ideation, suicide attempt, Current medications, healthcare utilization, lifetime mental health treatment (age of onset, duration, type, hospitalisations); perceived efficacy, adherence; current mental health treatment, orientations towards digital technology and interventions; goals for intervention, user preferences; perceived efficacy of intervention; Family history of mental/emotional problems; adverse childhood experiences; childhood trauma, high current stress severity, recent stressful life events, stress reactivity; Agreeableness; alexithymia; conscientiousness; emotionality; extraversion; hopelessness, openness, attachment style, self-esteem, perceived control, problem-solving ability, mastery, resilience; relationship quality; social networks; loneliness.

Whilst this is quite a lengthy baseline, they are similar in length to our previous ECoWeB study that was completed by 3800 young people. The battery has been programmed and tested by the CTU and a set of 6 students have tested it and provided feedback. Whilst noting it was relatively long, most students indicated it was clear, accessible, interesting and that they would be willing to complete it.

3.3 Outcome measures

Table 7 Outcome measures for Nurture-U Internet-CBT trial

Measure	Description	Reliability and Validity
PRIMARY OUTCOME (JOINT)		
Patient Health Questionnaire-9 (***PHQ-9***; Kroenke et al., 2001)	9-item participant rated questionnaire assessing frequency of symptoms of depression over the last 2 weeks. 4-point scale for each item, with anchors at 0=not at all, 1 = several days, 2= more than half the days, 3 =nearly every day. Unidimensional scale.	Leading measure of depression widely used in clinical trials, clinical practice, and as part of the NHS Quality and Outcomes Framework (QOF) for UK primary care, and Improving Access to Psychological Treatments (IAPT) Minimum Data Set (MDS). Cronbach's α =0.89 in primary care, test-retest reliability (ICC) 0.84 after 48 hours. Validation studies indicate positive correlations with measures of functional status (r=0.73), disability days (r=0.39), and symptom-related difficulty (r=0.55) At cut-off of ≥ 10, excellent specificity (0.88) and sensitivity (0.88) with diagnoses of major depression by structured interview, replicated in a UK population (sensitivity 0.80; specificity 0.92).
Generalized Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006)	7-item participant rated questionnaire assesses frequency of symptoms of anxiety over the last 2 weeks. 4point scale for each item, with anchors at 0=not at all, 1 = several days, 2= more than half the days, 3 =nearly every day. Unidimensional scale.	Leading measure of anxiety widely used in clinical trials, clinical practice, and as part of the UK NHS IAPT MDS. Cronbach's α =0.92, test-retest reliability ICC = 0.83. Convergent validity good, r =.72 with Beck Anxiety Inventory, r = 0.74 with Symptom Checklist-90 anxiety scale.

Measure	Description	Reliability and Validity
SECONDARY OUTCOMES		
Warwick-Edinburgh Mental Well Being Scale (**WEMWBS**; Tennant et al., 2007; Stewart-Brown et al., 2009)	7-item participant rated questionnaire assesses psychological and eudemonic well-being, each rated on a 4 point scale, with anchors at 1= None of the time, 2= Rarely, 3= Some of the time, 4= Often, 5 = All of the time. Unidimensional scale..	Leading measure of well-being. 14-item version validated from age 16 upwards; Cronbach's α =0.89, test-retest reliability ICC over 1 week = 0.83. Good convergent validity: positive correlations with EQ-5D VAS, PANAS-PA, satisfaction with life scales (all r's >0.72); negative correlations with PANAS-NA and GHQ-12 (r >-0.53).
Work and Social Adjustment Scale (WSAS; Mundt et al., 2002)	5-item participant rated questionnaire assesses impaired functioning, rated from 0 not at all impaired to 8 severely impaired, with respect to work/education, home management, social leisure, private leisure and close relationships. Unidimensional scale.	Leading measure of functioning, widely used in clinical practice, and as part of the UK NHS IAPT MDS. Cronbach's α range from 0.70 to 0.92, test-retest reliability ICC = 0.73. Interactive voice response administration correlated 0.81 to 0.86 with clinician interviews.
Use and application of intervention	Developed for study (3-items)	Use and application of intervention
Satisfaction with intervention	Adapted Client Satisfaction with Treatment Questionnaire-8	
Use of services /treatment received– questionnaire to be developed incorporating NHS and student services	To understand level of treatment sought and received – from list of student, NHS, and other options	Use of services /treatment received– questionnaire to be developed incorporating NHS and student services
5-item Brooding scale (see A in appendix below)	Secondary outcome	Test whether intervention reduces worry and rumination

Measure	Description	Reliability and Validity
Short-form Penn State Worry Questionnaires (see B in appendix below)	Secondary outcome	Test whether intervention reduces worry and rumination
Brief Resilience Scale (see J in appendix below)	Secondary outcome	As in Prevention trial
Academic grades self-report (see K in Appendix below)	Secondary outcome to assess impact on academic studies	As in Prevention trial
Use of services /treatment received– incorporating NHS and student services (see O in appendix below)	To understand level of treatment sought and received – from list of student, NHS, and other options	As in Prevention trial
Use and application of intervention	"How many days in the past 3 months did you log on and use the internet therapy"? Response options 0-90 "How many days in the <u>past month</u> did you use any of the skills you learned in the internet therapy?" Response option 0-30 "On average about how many times per day do you use these skills?" (0+)	NEW TO ACUTE TRIAL AS BOTH ARMS INVOLVE TREATMENT

Measure	Description	Reliability and Validity
	"In the past month, how helpful were the skills you learnt in the internet treatment?" Response options – very helpful; somewhat; a little; not at all helpful; they made things worse	
Satisfaction with intervention	Adapted Client Satisfaction Questionnaire – Internet-based interventions (Bos et al., JMIR 2016) Scored 1= "Does not apply to me" to 4="Does totally apply to me. Replaced "service" with "training" – may adapt to "therapy" 1. The online therapy was of high quality 2. I received the kind of therapy I wanted 3. The therapy has met my needs 4. I would recommend this therapy to a friend, if she or he were need of similar help 5. I am satisfied with the amount of help I received 6. The therapy helped me deal with my problems more effectively 7. In an overall general sense I am satisfied with the therapy	

Measure	Description	Reliability and Validity
	8. I would come back to this therapy if I were to seek help again Plus How much did this treatment help with the specific problem that led you to therapy? Made things a lot better 1, made things somewhat better 2, made no difference 3, made things somewhat worse 4, made things a lot worse 5	
Open text questions about therapy	1. What did you find most helpful about this therapy? 2. What did you find difficult or unhelpful about the therapy? 3. How could the therapy be improved?	
BACKGROUND AND DEMOGRAPHIC MEASURES [not including moderator variables]		
Educational achievement	Academic outcomes from students either via Self-report or consent to access student records	
AEQ Adverse Events Questionnaire	The Adverse Events questionnaire is a brief measure designed to assess stressful events in young people, relevant to the population under study in the current cohort (Carver, 1998). It consists of 3 questions asking about relevant	Carver (1998) found that this measure predicted subsequent depressive symptoms six weeks later in undergraduates and interacted with cognitive vulnerability factors to predict

Measure	Description	Reliability and Validity
	adverse experiences (bad experiences concerning academic study; bad experiences concerning relationships; other bad experiences) rated from 0 “No”, 1 “yes, happened once”, 2”yes happened twice”, 3 “yes, happened more than twice”. A fourth item asks about minor problems or hassles ranging from 0 “minor problems” to 4 “large number of minor problems and hassles”. We used the measure to assess levels of stress concisely and to examine whether stress is a potential predictor of subsequent depression and a moderatro of any treatment effects. We adapted the questionnaires to include work experience as well as academic study and to be focused on last 3 months, and added a separate question about changes or transitions in life.	depression, as did Beevers and Carver (2003) in a subsequent study,
Current medications, healthcare utilization, lifetime mental health treatment (age of onset, duration, type, hospitalisations – CIDI);		Treatment use
high current stress severity, stress reactivity (perceived stress scale);	Perceived Stress Scale (PSS)[38,39] 7 items; PSSI	Stress
Brooding subscale of Ruminative Response scale (5-item)		Coping styles

Demographic information will be collected at baseline including age, sex, country of birth, country where currently reside, ethnic group, educational level.

Additional measures: potential mediators of clinical outcomes

We will assess potential mediator of intervention by providing brief measures weekly for 8 weeks post-randomisation, taking less than 5 minutes to complete.

Table 8 Mediator measures for Nurture-U Internet CBT Trial – see also Appendix B

Measure	Rationale	Further information
PHQ-2 (see L in appendix)	Brief measure of depression	2-item scale
GAD-2 (see L in appendix)	Brief measure of anxiety	2-item scale
Stress **How much stress have you had in your life over the <u>past 7 days</u>?** (StressSev). Scored as: Very severe (4), severe (3), moderate (2), mild (1), none (0), list with circle to select	Single item to assess stress	laid out with ratings as choice buttons along horizontal paralleling other questions in this section
During the past 7 days in a stressful or upsetting situation: a) How often did you take a moment to question your interpretation of what was happening when you got upset (e.g., look for a more positive or balanced explanation; weigh up different accounts, try and put things in perspective)?	Use of cognitive and behavioural skills, 6-items, these reflect different potential strategies that individuals may use and that may be provided within the intervention	Brief questions to capture cognitive and behavioural strategies from Cognitive and Behavioral Response to Stress Scale (CB-

0= Never, 1=Rarely, 2=Occasionally, 3=Sometimes, 4=Often, 5= Very often, 6= Always; (b) How helpful was this in making you feel better? 0=Not at all helpful, 1 = Slightly helpful, 2=Somewhat helpful, 3=Moderately helpful, 4= Fairly helpful, 5=Very helpful, 6=Extremely helpful, N/A=Didn't do this last week During the past 7 days in a stressful or upsetting situation: (a) How often did you plan and/or do activities you knew you would enjoy? 0= Never, 1=Rarely, 2=Occasionally, 3=Sometimes, 4=Often, 5= Very often, 6= Always; (b) How helpful was this in making you feel better? 0=Not at all helpful, 1 = Slightly helpful, 2=Somewhat helpful, 3=Moderately helpful, 4= Fairly helpful, 5=Very helpful, 6=Extremely helpful, N/A=Didn't do this last week During the past 7 days in a stressful or upsetting situation: (a) How often did you use relaxation or similar techniques to soothe, focus or calm yourself (e.g., meditation, breathing, focusing attention, imagery)? 0= Never, 1=Rarely, 2=Occasionally, 3=Sometimes, 4=Often, 5= Very often, 6= Always; (b) How helpful was this in making you feel better?		RSS) Miner et al., 2015, with addition based on student feedback, see Appendix M for example of questionnaire

0=Not at all helpful, 1 = Slightly helpful, 2=Somewhat helpful, 3=Moderately helpful, 4= Fairly helpful, 5=Very helpful, 6=Extremely helpful, N/A=Didn't do this last week		
During the past 7 days worry is something that "I do automatically" "I do without thinking" "I start doing before I realise I'm doing it" Each of 3 items rated on 1 to 7 scale from Strongly disagree to Strongly agree [Strongly disagree, Moderately Disagree, Slightly Disagree, Neither Agree or Disagree, Slightly Agree, Moderately Agree, Strongly Agree)	Change in habit applied to worry, 3 items – to assess whether rumination/worry becomes more or less of a habit; the intervention focuses on changing habit	Adapted items from SRHI index, Gardner et al., 2012, laid out with ratings as choice buttons along horizontal paralleling other questions in this section
During the past 7 days problem solving is something that "I do automatically" "I do without thinking" "I start doing before I realise I'm doing it" Each of 3 items rated on 1 to 7 scale from Strongly disagree to Strongly agree (Strongly disagree, Moderately Disagree, Slightly Disagree, Neither Agree or Disagree, Slightly Agree, Moderately Agree, Strongly Agree)	Change in habit applied to problem-solving, 3 items – to assess whether more helpful responsive becomes more or less of a habit	Adapted items from SRHI index, Gardner et al., 2012, laid out with ratings as choice buttons along horizontal paralleling other questions in this section

Please indicate how often you behaved in the stated manner during the past 7 days on a scale from 1 (Almost never) to 5 (Almost always). "When I'm going through a very hard time, I give myself the caring and tenderness I need"; "When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people"	Self-compassion, 2-items; the intervention includes a self-compassion element	Selected items from SCS-SF (Self-Compassion Scale – Short Form), items from Self-kindness and Common humanity scales – see N in appendix for example of shortened questionnaire
2-items from Brooding questionnaire – "Indicate whether you never, sometimes, often or always thought or did each of the following when you felt sad, down or depressed over the past 7 days. A. Think "Why do I always react this way?" B. Think "Why can't I handle things better?"	Rumination, 2-items	Adapted from the RRS-B-Brooding 5-item questionnaire, Treynor et al., 2003, see Appendix A for the full questionnaire – this uses two items from it
"In the last seven days I feel better prepared to handle situations I could not handle before" rated using a seven-point Likert scale ranging from −3 ("absolutely not true), 0 ("neither nor") and +3 ("absolutely true").	Self-efficacy/Mastery	Laid out as horizontal rating scale underneath the description item
"In the last seven days, I understand myself and my problems better" rated using a seven-point Likert scale ranging from −3 ("absolutely not true), 0 ("neither nor") and +3 ("absolutely true").	Problem clarification	Laid out as horizontal rating scale underneath the description item

3.4 Primary endpoint/outcome

The primary endpoint of the trial is at 3 months post randomisation.

3.5 Secondary endpoints

There is no other endpoint.

3.6 Exploratory endpoints

There are no exploratory endpoints.

3.7 Endpoints/outcomes

Table 9 Endpoints/outcomes

The following table displays which measures are collected at each of the assessment points:

Measure	**Detail**	**Size**	**Screener**	**Baseline**	**3 months**
PHQ9	As screening measure i.e., > 9 meeting caseness. Sample needs to have elevated depression and/or anxiety. Primary outcome measure;	9-item plus 3 conditional risk questions to suicide question	X	X	X
GAD-7	As screening measure i.e., > 9 meeting caseness. Sample needs to have elevated depression and/or anxiety. Primary outcome measure;	7-item	X	X	X
LIDAS well-validated self-report questionnaire /interview means of checking current diagnosis inclusion exclusion criteria items	Part of the moderator measures given pre-randomization. Including anxiety and depression to capture both history of anxiety and depression and current diagnosis	Conditional questionnaire asked ever and last 3 months ranging 4 questions to 22 depending on answers 3 Conditional risk questions 7 other items On past health;	X	X	X, last 3 months

Self-reported check on history of diagnosis	No history of drug/alcohol/ substance dependence; exclusion criteria		X		
Self-reported check on history of diagnosis	No history of psychosis; exclusion criteria		X		
Self-reported check on history of diagnosis	No history of bipolar disorder; exclusion criteria		X		
Self-reported check	Not currently receiving psychological treatment at point of entry into study; exclusion criteria		X		
Question re university of study (drop-down list – with 6 primary universities then other -with text option)	University student - Necessary to provide independent informed consent		X		
Age	16 or older - Necessary to provide independent informed consent		X		
Access to PC/smart phone/internet	Necessary for delivery of intervention		X		
Gender identity (M/F/neither/both); sexual orientation, race/ethnicity;	Demographic measures to explore diversity of sample and representativeness against student body AND to include in moderators			X	

birthplace, educational attainment, topic of study	as potential predictors of treatment response				
Past history of depression;	Obtained from LIDAS or equivalent – to include in moderators as potential predictors of treatment response			X	
Current medications, healthcare utilization, lifetime mental health treatment (age of onset, duration, type, hospitalisations – CIDI);	to include in moderators as potential predictors of treatment response			X	
high current stress severity, recent stressful life events (AEQ), stress reactivity (perceived stress scale; PSS);	to include in moderators as potential predictors of treatment response			X	
Five factor short-form	Measure of personality	10-item		X	X
WEMWBS	Secondary outcome	7-item		X	X

5-item Brooding scale	Possible moderator and also potentially influenced by intervention	5 items	X	X	X
Short-form Penn State Worry Questionnaires	Possible moderator and also potentially influenced by intervention	7 items	X	X	X
WSAS	General Functioning	5-item		X	X
AEQ /stress (PSS, ATQ)	Adverse events/stressful life events	5 item, 5 item			X
Self-report or consent to access student records	Academic records/ Self-reported academic outcomes				X
Use and application of intervention		Developed for study (3-items)			X
Adapted Client Satisfaction with Treatment Questionnaire-8	Satisfaction with intervention				X
Use of services /treatment received– questionnaire to be developed incorporating NHS and student services	To understand level of treatment sought and received – from list of student, NHS, and other options			X	X

4 TRIAL DESIGN

Design
We will undertake a Phase III superiority parallel 2-arm randomised multicentre randomized controlled trial. Our study design follows MRC Complex Interventions Guidelines and the theoretical mechanisms targeted by intervention have been confirmed. The design of the trial is illustrated in **Figure 1**.

Conditions*.* Appropriate participants (see inclusion/exclusion criteria below) will be randomly allocated on 1:1 to the following two conditions using an intention-to-treat (ITT) approach:

(A) Offered an unguided internet-delivered transdiagnostic CBT package via an online platform in addition to usual practice

(B) Offered a guided internet-delivered transdiagnostic CBT package via an online platform in addition to usual practice

Assessment points*.* Within the prospective cohort, the same outcome measures will be obtained at baseline (M0), 3 months (M3) follow-up.

5 TRIAL SETTING

The recruitment centres are the University of Exeter, UK, which provides the coordinated central hub through which participants will be screened, randomised, data collected, treatment offered and follow-up assessments delivered, and the other universities in the project, who will all provide sources of recruitment into the study (e.g., advertising the study locally, in lectures, via websites, via social media): University of Oxford, University of Cardiff, King's College London; University of Newcastle, University of Southampton. There will also be an option for students to access the trial from other universities [Other option, e.g., direct response to social media advertising).

All participants will be directed to the trial recruitment website where they can find out more information about the study. Those interested will then link to the screening and electronic data capture platform, where their eligibility will be assessed with a brief set of measures – if eligible, the participants then proceed to give full informed consent and complete the baseline assessment. The interventions will be provided through a licensed internet provider in which the CBT treatment is configured in the content management system: at randomisation, participants will be given access to the internet platform and encouraged to sign up. Follow up data will be collected online through the programmed electronic data capture system (EDC) and then collected by, stored, and organised by the Exeter CTU.

Researchers at each site will promote participation in the study. All queries, intervention and assessment follow-ups will be dealt with centrally from Exeter. All processes are centrally run from Exeter. The only role and responsibility for the other universities is to advertise and publicise the trials – alongside other activities they are doing for the wider Nurture-U project.

6 PARTICIPANT ELIGIBILITY CRITERIA

The sample will be a selected group of university students (no age limit, as long as able to provide informed consent, i.e., older than 16), who have current anxiety and/or depression as indicated by caseness on standardised measures (PHQ-9 and/orGAD-7).

We will exclude those individuals who do not have sufficiently elevated anxiety and depression– as the primary outcome is treatment of anxiety and depression, we need to exclude those without elevated symptoms. Those with history of mania or psychosis will not enter the trial and will be directed to their GP and signposted to national and local services. We will monitor screening and demographic information (age, gender, ethnicity) across included and excluded participants to inform the implementation phase. Those excluded for lacking elevated anxiety and depression but who are eligible for other trials will be directed to those trials during the screening process (e.g., Nurture-U prevention trial).

6.1 Inclusion criteria

Inclusion criteria

(1) Aged 16 plus based in the UK, attending university (predominantly one of the six partner universities or other HE institution or associated HE institution, e.g., Falmouth University for University of Exeter).
(2) Reporting PHQ-9>9 and/or GAD-7 >9
(3) basic literacy in English as indicated by ability to complete consent and online questionnaires (12 year old reading age or better).
(4) Ability to provide informed consent
(5) Available for the full duration of the study (3 months)
(6) Regular access to a relevant smartphone / tablet / laptop or PC able to run the intervention (using android or IOS systems)

6.2 Exclusion criteria

Exclusion criteria

(1) Meeting criteria on self-report electronic screening questionnaires for any of the following
    a. active suicidality; or
    b. any history of severe mental health problem (i.e., bipolar/psychosis/mania/drug/alcohol dependence);
(2) Currently receiving psychological therapy or counselling (this would include treatment provided within a clinical service or university wellbeing service or participation in another clinical trial)*
(3) Currently receiving antidepressants or other psychiatric medication that has been changed within the last 4 weeks (in this instance the participant has the option to join the trial once stable for 4 weeks).

*We considered whether prior use of Silvercloud should be an exclusion criteria, but we decided against this because (a) it would be arbitrary to exclude one variant of CBT but not others; (b) it would reflect more real-world versimulitude to include; (c) use and attitudes to interventions will be assessed at baseline.

7 TRIAL PROCEDURES

University students meeting inclusion criteria will be enrolled in the cohort via the study website and electronic data capture platform. Once enrolled and consented, each participant will be followed for a minimum of 3 months, with assessments at baseline and 3 months. UNEXE will have overall responsibility for the monitoring of the delivery of the recruitment and retention into the cohort.

All baseline assessments will be online through a serious of questionnaires created within the EDC system. The trial website will host a welcome screen with Instagram feed and informational videos. The website will link to the privacy and data protection policy for the trial and this will be downloadable.

The EDC system will host:

- Pre-screening. There will be a set of pre-screening questions to quickly check if participant may be eligible for the study (and for other Nurture-U trials [if depressed and/or anxious – see ***Table 7*** for details). Participants complete a brief consent to complete these measures. Those meeting eligibility than proceed to the full consent and baseline measures. Full details of the questions asked and information provided in the help pages can be found in Appendices.
- In the consent (a) questionnaire the information sheet will be presented and consent form with fields for completion. Consent A asks for consent to take part in the screening assessment for the trial. Recruits will be asked for their contact details during the consent process and if consent is given then they can screen for eligibility and are assigned a Screening ID number unique to them. The recruit will automatically be emailed or be provided a copy of the information sheet, the privacy policy and the consent form for their records.
- Those excluded will be automatically routed to pages detailing why, with links to sources of help. There will be pages tailored for suicide risk, mania/psychosis.
- Those consenting to complete the screening will be asked to complete a series of screening questionnaires designed to assess their relevant eligibility.
- At the end of the screening assessment participants will be asked to consent to take part in the trial if meeting eligibility criteria.
- Participants can at any time during the assessment save what they have done and will have been emailed when they gave consent A so that they can complete their assessment in stages. The link is live for 2 weeks so they have that long to complete the assessment and read the materials before consenting to take part in the trial (consent b). Two weeks was chosen as some of the questionnaires ask about wellbeing in the last 2 weeks so if the time period was longer, those results would be out of date.
- Once participants have met eligibility criteria at screening and consented to join the trial, they will be asked to complete the baseline assessment consisting of relevant demographics, potential moderator measures and outcome measures.
- When the participant has completed their baseline assessment, a trigger is sent to the CTU database which signals it to collect all the participant's data through the EDC.
- A message is also sent to participants to confirm that they have completed the assessment.
- When participants have consented to take part in the trial and completed their baseline assessment, they will be randomised into one of the 2 conditions: guided versus unguided i-CBT, and assigned a new study ID number unique to them. All participants receive one or other form of the internet treatment.
- The proposed process for consenting participants to access the internet treatment is via being signed up into the platform by a therapist/administrator who can add the patient to the platform using their email address via the dashboard. This will require an automated message to the relevant staff member informing them of need to set-up participant, with access to protected database to do so. It also requires an email to go to participant to inform him/her of their randomisation and what will happen.
- Participants will set their own password and work through the treatment package at their own pace with or without support from the therapist/psychological wellbeing practitioner subject to randomised arm. Access to the intervention will be monitored by the therapist – who will provide feedback and contact to those who are randomised to the support system. Participants in both guided and unguided i-CBT will receive automated reminders from Silvercloud to complete modules, reminder emails from therapists if they have never logged into the system or if there are longer gaps in logging in to modules (using a SOP with equivalent timings for both arms).

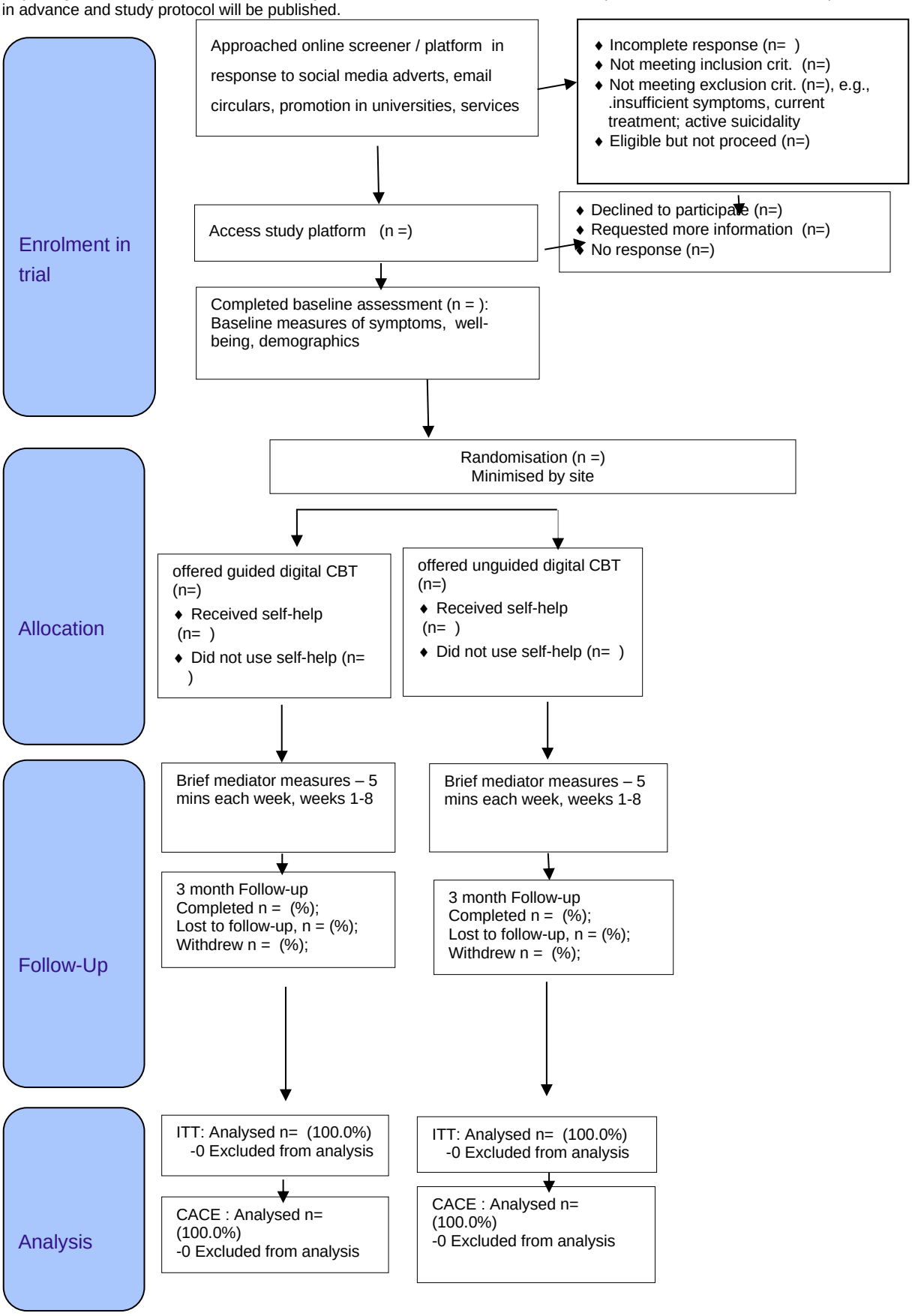
- The Exeter EDC system will host the follow up assessments and the system will automatically email reminders to participants with a link to access the site so that they can complete follow ups at month 3 months. The data will automatically be collected and stored on the EXCTU database.
- The mediator questions will be sent out weekly from week 1 to week 8 post-randomisation.

7.1 Recruitment

Recruitment strategy

The consort diagram for the full trial can be found in **Figure 2**:

Figure 2 CONSORT FLOW DIAGRAM for guided vs unguided i-CBT ACUTE Treatment randomised controlled trial
Reporting of the study and of statistical analyses will follow the CONSORT standard (Schulz, Altman, & Moher, 2010). Trial will be registered in advance and study protocol will be published.



7.1.1 Participant identification

We will recruit from the general university population initially across the 6 partner Universities in the grant. Posters, emails, websites, presentations, and social media will all advertise the study for students who wish to tackle anxiety and depression. The recruited sample is likely to be predominantly female based on prevalence of risk for anxiety and depression and prior studies; we will actively seek to recruit more male participants.

Recruitment of the cohort will follow successful models (e.g., http://www.mappiness.org.uk/, 66,000 participating). Using proven methods, researchers will recruit participants through:

- multiple traditional and social media (posting and advertising on Facebook, YouTube, Instagram, SnapChat, Google, MySpace, Twitter, TikTok, study website, through media influencers/vloggers, etc adjusted by cost/frequency as needed); social media analytics will be used to enhance recruitment;
- app store, Googleplay store;
- email circulars and local promotion (posters, emails, newsletters, signposting by staff) to university departments;
- snowballing approaches;

The internet, a national digital community available anywhere at any time, overcomes access difficulties due to geographical location, cost, poor mobility, lack of time, and supports privacy. Self-referral avoids potential “gatekeepers” to help and other potential barriers such as requiring access to services. It is consistent with young adult’s high internet usage. For example, in 2015 in the UK, 91% of 16-24 year olds had home internet connection; 90% had a smartphone (Ofcom, 2015). Research generally shows familiarity with and positive approach toward digital media in adolescents (Oh et al., 2008).

All partner universities will recruit to electronic surveys and RCTs. For each of the survey, online MHL course, and RCTs, following student-led engagement/awareness campaigns, we will invite relevant students at each university into the study via campus emails, local advertisements, social media and recruitment websites and ask them to consent electronically to participate.

We will work with our Student Advisory Group to develop engaging and meaningful student-led engagement and recruitment campaign materials for the trial. We will also use the wider campaign for the overall project and parallel studies to support recruitment into the trial – for example, we will seek for 1000s of students to complete our mental health survey x 2 times a year and this will include measures that can signpost relevant participants to this trial. Similarly, for greater efficiency, there will be transfer between workstreams (e.g., students in survey scoring above symptom cut-offs directed to RCTs; those excluded from one RCT directed to other RCTs if appropriate).

The student mental health project will activate accounts in several social media to provide information about the project, linked to the Nurture-U brand. These accounts will be used to aid recruitment in the trial:

- YouTube:
- Twitter:
- Facebook:
- Instagram:
- Vimeo:
- Linkedin:
- Google

- TikTok

No participants will be recruited through or at NHS or medical organisations or personnel.

In response to promotion and advertising or word-of-mouth, potential participants click on a link that goes to study website that provides information about the study. This also provides access to the trial electronic platform which provides screening for suitability in a logical conditional sequence. Individuals who met these eligibility criteria proceed to more detailed information and provide consent to join the trial. The baseline assessment is automatically provided through this electronic platform. We will ask about usual care received by participants at baseline and then again at follow ups. Once judged eligible for the study and having consented to participate, a participant is randomised and set-up on the intervention if randomised to that arm.

Past evidence
Our multiple recruitment routes have each proven effective. Online and social media advertising is effective (1500 participants recruited for well-being study over 2 months via Facebook adverts, Cobb & Poirier, 2014). We have good evidence on conservative estimates that we can recruit at an approximate rate of 14 young persons per week at each site on average, making feasible an overall target of 720 participants recruited into the cohort over 18 months. In previous digital intervention studies in the UK, we recruited on average 14 participants per week for internet treatment using Facebook adverts and at least 20 a week using email circulars to universities for a self-help mental health intervention for undergraduates (Freeman et al., 2015). In the ECoWeB project, we principally recruited through social media advertising and through circulations within universities and we recruited n=3800 across 4 countries (n=1200 in UK only) across 9 months.

7.1.2 Screening
Participants will be screened by an EDC system set-up and managed by Exeter CTU for university students - those under 16 will automatically be screened out pre-assessment. Website users who report having current risk will be taken to the feedback screen where they will be advised that we are sorry to hear that they are feeling that way, to please contact their GP and to give them sources of online help and support.

7.1.3 Payment
Participants will be paid in electronic vouchers for taking part in the mediator and follow up assessments; we will pay 10 pounds for completing the mediator assessments and the 3 month follow up.

Researchers will be able to run reports on the Exeter CTU database to identify which participants have completed follow ups at the key payment points (after 3months). Site researchers will arrange for the payment of participant using electronic shopping vouchers, which can be emailed or sent by text or via direct bank transfers. No travel expenses are anticipated for participants as all assessment and intervention contents are provided remotely via digital platforms (website, app).

7.2 Consent
We anticipate that university students will be autonomous independent young adults who are legally recognized as being at or above the age of majority and able to provide their own informed consent to their participation in research (aged 16 or over for the UK).

Young people will be initially routed to or seek out the study website and will be provided with the participant information sheet (which will be submitted with the protocol), consent form A and data protection policy to review on the trial electronic platform, prior to completing screening measures. There will be a check box at the bottom of the information sheet which participants will need to check before

they can sign the consent form. Participants will then be asked to read, date, and electronically sign consent form A and provide their contact details. Consent form A asks for consent to undertake the assessment and confirmation that the participation understands the nature of the study (the consent forms will be submitted for review with this protocol).

When consent is given, they will automatically be emailed a copy of the consent form, information sheet and data protection /privacy policy or given the option to download these documents. The recruit will then be asked to complete brief background screening measures to determine eligibility on the online screening website. Non-excluded recruits can stop and save their assessment at any time and be emailed a link to return to the assessment. The participant will have 2 weeks in which to be able to return to their part completed assessment. After this time, they would need to start the assessment again if they wanted to take part.

If a participant completes the screening assessment and is eligible for the trial, then they will be presented with consent form B2 which asks them to consent to taking part in the trial. Recruits are advised that they can take time to consider taking part and can save their assessment whilst they do so.

On completion of consent form B2 participants are then asked to complete the full baseline assessment measures. Once this has been completed, the recruit is randomised and given a unique participant trial number, and they are informed that they have completed the baseline assessment and that they will be contacted to be informed of the outcome of the randomisation.

All participants will be given the option to seek further information from the research team, with contact details to the relevant research team provided (email, and/or telephone number as available). This information will be provided on all versions of the information sheet and on the help menu of the study website.

Our proposed procedures for recruiting and screening students have previously been approved by local and national ethics committees, and we will obtain approval before commencing the study. The sponsor will take out civil liability insurance to protect participants.

7.3 The randomisation scheme

At the point of randomisation participants will be automatically registered on to the trial using the EDC system. Randomisation is after the online consent, the screening process and after the online baseline assessment. There is a two-part consent process which in the first part asks for permission to screen and take part in the assessment. The second part of consent at the end of the screening assessment asks for agreement that the participant wants to take part in the main study. Participants can stop the assessment at any stage and be emailed a link to return the screening website. This allows them to have time to consider the participant information which they have read on screen and which is emailed to them. The email link will be live for 14 days. After this time the participant will need to contact the site to ask for the link to be reset.

Random selection to the 2 arms (unguided vs guided i-CBT) will be conducted automatically by means of a secure service created and managed by the Exeter Clinical Trials Unit (CTU) in conjunction with the trial statistician. This will be independent of the trial researchers. To promote balance across key participant characteristics across groups, we will stratify allocation to trial site (reflecting source of recruitment – Exeter, Oxford, Southampton, Newcastle, KCL, Cardiff, Other). To maintain concealment, the stratification algorithm will include multiple blocks ranging in size from 4 to 6 participants.

Protection from bias
We will adopt prior registration and publication of the trial protocol. Independent web-based computerised randomisation will be conducted to ensure generation of an unpredictable allocation sequence and concealment of participant allocation and of allocation sequence and prevent selection bias and confounding. We will use standardised assessments with data collected automatically through the website. The use of self-administered measures will eliminate observer bias. A detailed statistical analyses plan will be prepared and agreed with Trial Steering Committee and Data Monitoring and Ethics Committee before any analysis is conducted. The trial statistician will remain blinded to group allocation until the main data analyses have been undertaken and interpretation of the trial results have been agreed by the relevant committees. Attrition bias will be minimised by having robust trial procedures to prevent data loss such as email, text, and phone reminders to encourage follow ups.

7.3.1 Method of implementing the randomisation/allocation sequence

Participants will be randomised by a programmed system which interfaces with the Exeter CTU EDC system and database. This will be an automated process. The Exeter CTU EDC system will contact an unblinded team member (administrator/therapist) indicating when an individual [by study ID] has been randomized to either of the active interventions. This team member will then access the relevant details in the Exeter CTU database and manually set up the participant in the internet platform using administrator rights via the internet platform dashboard. An email will also need to go to the participant indicating the condition to which they are randomised and informing them what to expect. The relevant unblinded team member will also be able to monitor if the participant has accessed the intervention and check if there are any difficulties and encourage to sign-up.

Detailed procedure for randomisation:

1. Participants are randomised on a 1:1 basis into the 2 arms on an intention-to-treat basis: unguided plus guided i-CBT. Site is used for stratification.

2. The system must record the allocation and the date randomised.

3. The trial manager and at least one other researcher remain blind to the allocation; the participant will be aware of which intervention received. Thetherapist/administrator will be unblinded in order to set-up participant on internet platform.

4. On successful randomisation, a finish page is displayed with a message telling the participant to look for an email message from the trial team.

7.4 Blinding

The follow up data will be routinely collected online using the website/EDC system (and the reminders for this will be sent out automatically by email from the EDC system). This will prevent the follow up results being affected by the researcher.

Trial researchers who will be blind to treatment allocation include the Chief Investigator and Trial Manager. The Trial Manager will be in direct contact with participants to answer technical queries. The trial therapists will be unblinded and will be in direct contact with participants to follow up risk. It is possible that a researcher could become unblinded during those (infrequent) conversations if the participant mentions details of the intervention.

Should a blinded researcher become unblinded then this will be logged as an unblinding and any telephone-based chasing of follow up data for that participant in future will be conducted by another blinded researcher (if available). Therefore, only blinded researchers will attempt to collect the primary outcome measures by telephone if the participant is unwilling to use the electronic platform for this purpose. Unblinded researchers will not discuss information relating to condition with blinded researchers. During any contact with participants the blinded researcher will remind them not to divulge to which condition they were allocated. In the event that there are no unblinded researcher and telephone collection of follow up primary outcome is possible, this data will be collected, but will be logged and clearly marked as 'collected unblinded'. This will allow the statisticians to control for this in their analysis. The statisticians and the Steering Committee will be blinded to intervention until the analysis is done and they are interpreting the results.

7.5 Emergency Unblinding

It is extremely unlikely that a researcher other than the administrator/therapist responsible for setting participants up on the intervention would need to be unblinded, even in cases of risk. The trial code would only need to be broken for valid medical or safety reasons, for example in the case of a serious adverse event, where it is necessary for the investigator or DMEC to know whether there is a relationship between condition and adverse events. In these circumstances, the research team will remain blinded. Where a person raises clinically relevant concerns or reports risk, and where knowing the trial condition is relevant, one of the project team dealing with this participant can potentially be unblinded to the participant's condition to support their care and further support them – in many cases, it may not be necessary to know the condition. The action taken according to the risk protocol would be the same, regardless of condition. The PI will be able to request the condition from the CTU if there are any adverse events. In the case of a serious adverse event, it will be necessary for principal investigator / site-relevant clinician to be unblinded for safety reasons and for accurate reporting onto the DMEC.

The DMEC will be unblinded in aggregate to cases of serious adverse events (i.e., knowing condition for those reporting serious adverse events, but no other personal information) to have an overview of the relationship between condition and risk.

7.6 Baseline data

The CRF for the collection of baseline is available as a separate Appendix. These data will be collected after the screening section of the screening website. The measures used have been described previously in Section 3.

7.7 Trial assessments

Assessment will take place at baseline and then at 3 -months post randomisation. The 3-month follow up will be the primary endpoint. All assessments will be through EXCTU managed EDC system.

Only if participants have not responded to email and text prompts to complete their follow ups at 3 months will they be contacted by phone and asked to provide the primary outcome measures only on the telephone. (We have found that in previous studies participants are often willing to provide these measures on the phone rather than complete the full online assessment).

The results of the assessments are only to collect research data for the trial and will not be provided to medical practitioners. The only exception to that would be if a participant indicates suicide risk and asks us to provide their assessment results to their medical practitioner. They would need to give written consent for this and provide us with the contact details to do so. See risk protocol in Appendices.

Table 10 The Schedule of Procedures

Procedures	**Screening**	**Baseline (at same time as screening)**	**3 month follow up**
Informed consent	Yes	Yes	Yes
Further Demographics	Yes DOB University	Yes Education level, ethnicity, sexuality	NO
Mental Health History	No	Yes	No
Current Physical conditions	No	Yes	Yes
Current medications	No	Yes	Yes
Eligibility assessment	Yes	No	No
Randomisation	No	Yes	No
Access to intervention	No	No	Yes
Compliance with intervention	N/A	N/A	Yes
Assessment of wellbeing and depression		Y	Y
Assessment of current functioning	N	Y	Y
Assessment of service use	N	Y	Y
Adverse event assessments	N	N	Y

Strategies to ensure retention in the study

Attrition is often high in internet studies, especially those solely conducted through electronic media (see Andrews et al., 2010; Van Ballegooijen et al., 2014). Based on previous studies including our guided internet study for rumination (74% retention at 36 months) and internet self-help feasibility study (70% retention at 15 months), where the greatest loss-to-follow-up occurred at first follow-up and only marginally declined between later follow-ups, we have powered for a 20% loss-to-follow-up at 3 months. This possible attrition has been factored into our calculation of power and sample size.

To maximise retention, we plan to update participants and other key stakeholders about the study's progress through social media and the study website. Participants will be offered an online/app voucher in recognition of their time spent on the completion of questionnaires and interviews. Follow-up attrition will be reduced by directly contacting participants through the website and by sending regular updates and news, and by obtaining (with participant permission), relevant electronic contacts (e-mail; mobile telephone), repeated automated attempts to contact, use of text reminders for completing follow-up assessments, and an honorarium for each completed assessment. These approaches have been effective in our previous trials. For example, in earlier studies using online interventions with adolescents we were able to retain 83% of participants in the intervention and 81% of participants in the study until the 12-month follow-up (Topper et al., 2017) and 70% of adults at 15 months (Montero-Mayin et al., 2016).

7.10 Withdrawal criteria

Participants can choose whether they want to stop using the internet intervention, or if they want to withdraw from the trial completely (including all assessments) at any time. Participants will also be withdrawn from the trial if the site clinical advisor, or the participant's medical practitioner advises that this is best for their wellbeing. A log will be kept of the participant number, reason for and date of all withdrawals from the trial. Participants who met the inclusion and exclusion criteria at baseline will not be replaced. Participants who did not meet the criteria at baseline can be replaced and their data removed from the data set. Participants who withdraw from the trial will not be followed up. Once a participant withdraws, all email and text notifications that are set on auto will be removed.

7.11 End of trial

The final follow ups are due by end of February 2025 and the project will end on 31st August 2025. Any early termination of the trial will be reported to the ethics committee, TSC and sponsor within 15 working days.

8 TRIAL ARMS

Unguided vs guided transdiagnostic digital CBT

The treatment will be an established internet platform that provides a standard transdiagnostic cognitive-behavioural approach to treating anxiety and depression, including proven elements such as activity scheduling, exposure to anxious situations, psychoeducation, thought challenging, behavioural experiments, relaxation, problem-solving, delivered via an online treatment platform (for example, there are well-established interventions provided by MindDistrict and Silvercloud – the interventions to be used will be the Silvercloud Space from Anxiety, Space from Depression, Space from Depression and

Anxiety packages as these are widely used in IAPT and university sector, with a focus on the combined transdiagnostic package).

The i-CBT will be delivered online and can be accessed on smartphone, tablet, PC, or laptop to maximise means to access self-help, to benefit from increased engagement by allowing users to choose their preference of which to use, and to utilise the relative advantages of the medium (portability for app). The intervention will include text, pictures, audio-recordings, animations, audio-exercises to practice, questionnaires with tailored feedback and quizzes. The content will focus on providing psychoeducation, tips, advice, strategies, and reflective exercises and learning tests relevant to tackle anxiety and depression.

Depending on the exact set-up of the internet CBT platform, the training will be split into weekly modules (typically 6-8) with participants encouraged to take approximately 1-2 weeks to work through each module. The internet package provides automated contingent feedback to the answers provided by the participants and it also sends automated reminders to participants who haven't logged into the intervention package each week.

The intervention will be identical by content and design between the guided vs unguided versions, except for the provision of support and contact from a CBT therapist (PWP) for the guided version. This therapist will provide weekly support/contingent feedback on completion of a module [i.e., asynchronous online feedback within the treatment platform], but can also be available for email contact from participants and for telephone/video review [i.e., blended model, subject to review with students for most engaging process]. Support and feedback will typically be relatively brief c. 15-20 mins per module per patient.

8.1 Trial restrictions

Participants will need to be aged over 16, resident in UK, and attending a UK university. Participants with suicide risk or a past history of psychosis or mania or substance/alcohol dependence at baseline will be excluded. Participants will need to have basic literacy in English, and access to a smart phone or computer or tablet to access the intervention.

8.2 Assessment of compliance with treatment

Brief questions during the 8-week mediator assessment will include questions about use of the intervention where appropriate.

There will be regular downloads from the internet-treatment platform, which will be compiled in a data base hosted by Exeter CTU. This will be to safeguard the data. This data will need to include both (a) user data – i.e., what the participant enters into the internet platform in terms of answers to questions and text boxes; (b) usage data – i.e., time spent on the internet platform, what completed and when. The therapist will monitor the progress of participants in the intervention so that any problems can be identified. If resources allow, site researchers may email, text or telephone participants who are not using their app to see if they need help downloading or using it.

9 ADVERSE EVENTS

Participant welfare and safety

There is no known health risk associated with any of the assessments or unguided/guided CBT. The risk concerning participation in this study is believed to be low. Further, we anticipate that the interventions will reduce symptoms and improve well-being and resilience. In our experience from previous projects, participants are happy to participate and enjoy the assessment tasks. We will strive to use tasks that the participants experience as motivational and reinforcing whenever possible. This will also ensure a low attrition rate. These interventions are already widely used in the NHS and the university sector.

The initial screening process will exclude anyone with current history of severe psychiatric disorder and those reporting elevated suicidality. These individuals will be automatically guided towards appropriate information and sources of help. This process means that individuals likely to have significantly increased risk (e.g., for self-harm and suicidality), and/or for whom more intensive psychological and psychiatric treatment is appropriate, will not be included in the study.

Other than the intervention failing to produce an effect, there is nothing in the literature to suggest possible adverse effects of the assessments and interventions for the young people involved. Versions of components within the intervention have been previously used with no detected harmful effect.

As with all psychological interventions, individuals reflect on their difficulties, which can produce temporary increases in distress, but no more than would commonly occur in daily life. Prior work has provided positive feedback on the i-CBT and indicated reductions in poor mental health over 3 months, with few serious adverse events reported: as such, the intervention within the trial may benefit individual participants. The likeliest outcome for users who do not find the intervention of benefit is their disengagement from it. In addition, all participants receive more intensive monitoring, with processes to identify and direct all relevant participants to potential sources of help.

As part of our policy for addressing risk and prioritizing the welfare of participants, participants are provided with links to online support, access to contact the trial team, and automatic signposting to help and guidance if reporting risk (e.g., suicidal thoughts, as indexed in items within outcome measures such as the Patient Health Questionnaire-9, PHQ-9 on the screening or follow-up websites) or levels of symptoms suggesting a need for help within any of the assessments within the cohort study. These messages include general information on the presenting symptom, recommended actions to make themselves safe, and advice to seek medical help, and direct links to relevant national sources of help (see Appendix A).

The main indicators of harm will be the completion of questionnaires by the participants at all assessments (baseline, 3 month). Questionnaires will be automatically screened for signs of severe distress (for example, defined reports of suicidal ideation), with automatic programmed questions following up to ascertain aspects of risk and to automatically provide users with recommended advice and signpost towards help (family doctor, local hospital, university wellbeing services, crisis teams, relevant charities; e.g., website link to the Samaritans). Other indicators would be report of worsening symptoms or suicidality in direct contact from participants to the research team or in contact with the trial therapist.

For all participants, we will include brief open questions to assess potential harm from the intervention (e.g., “How you have any problems with the internet treatment? Has any aspect made you feel worse?), whilst minimizing participant burden (at 3 month assessment).

Individuals reporting severe levels of symptoms or meeting diagnostic criteria for depression will be offered guidance to seek appropriate help from their GP/family doctor, occupational health or student well-being service should this seem necessary.

For those who enter the trial and then indicate risk there will be the option to contact a site researcher via e-mail or telephone to seek advice. This advice will include guidance to seek appropriate help from their GP/family doctor, occupational health or student well-being service should this seem necessary. Project researchers will be trained in and provided with a protocol to assess risk and with standard useful responses in these circumstances (see Appendix A). The University of Exeter trial site has a designated senior clinician(s) [clinical psychologist] and psychological wellbeing practitioners who will be available as a resource to researchers to provide guidance on clinical issues arising from participants either through standardized measures or contacts initiated by the participant. If the researcher has serious concerns about a participant, where appropriate, after discussion with the clinician, the clinician or researcher will contact the participants (by email, telephone) to review the situation, provide guidance and offer to write a referral letter, subject to participant consent. These procedures will be made explicit in all information sheets. Any concerns detected this way will be recorded on a standardised pro forma, a copy which will be sent to the DMEC and sponsor for the trial. The same process will be activated in response to any concerns raised by participants at other times, either spontaneously or in responses during the assessments.

We will record both serious and non-serious adverse events as defined by the National Research Ethics Service (e.g., deaths; self-harm; serious violent incidents, referral to crisis care or admission to psychiatric hospital) within both groups and report them to the DMEC and Research Ethics Committee to determine whether events are related to the treatments and to take appropriate action.

9.1 Definitions

Standard definitions for adverse events etc are in *Table 11* .

Because the current interventions are digital self-help rather than a medicinal product and involve no biological agent, it is not appropriate to define adverse events etc re any untoward medical occurrence – rather as a psychological intervention, appropriate adverse events would include those related to mental state and behaviour:

i) Serious adverse events (SAEs) including death, suicide attempt, self-harm, serious accident or violent incident, referral to crisis care or admission to psychiatric hospital.

ii) Adverse Events (AE) may include significant worsening symptoms of anxiety, worsening symptoms of depression, as operationalized by a reliable deterioration of movement from ‘mild’ to ‘severe’ or ‘moderate’ to ‘severe’ levels of symptoms on GAD7 or PHQ9 AND a change of ≥4 points on GAD7 or ≥6 points on PHQ9 from baseline assessment to 3 months assessment, new instance of self- harm, new instance of suicidality.

The following definitions are therefore adapted in light of this – see below.

Table 11 Definitions of Events

Term	Definition
Adverse Event (AE)	Standard: Any untoward medical occurrence in a participant to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product. *Adapted: Any deterioration in mental state or behaviour in a participant to whom the intervention has been administered, including occurrences which are not necessarily caused by or related to the intervention*.
Adverse Reaction (AR)	Standard: An untoward and unintended response in a participant to an investigational medicinal product which is related to any dose administered to that participant. The phrase "response to an investigational medicinal product" means that a causal relationship between a trial medication and an AE is at least a reasonable possibility, i.e,. the relationship cannot be ruled out. All cases judged by either the reporting medically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the trial medication qualify as adverse reactions. *Adapted: An untoward and unintended response in a participant to an intervention which is related to any dose of the intervention administered to that participant.* The phrase "response to an intervention" means that a causal relationship between an intervention and an AE is at least a reasonable possibility, i.e., the relationship cannot be ruled out. All cases judged by either the reporting appropriately clinically qualified professional or the Sponsor as having a reasonable suspected causal relationship to the intervention qualify as adverse reactions.
Serious Adverse Event (SAE)	Standard: A serious adverse event is any untoward occurrence that: • results in death • is life-threatening • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • consists of a congenital anomaly or birth defect Other ‘important events’ may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.

	NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.
Serious Adverse Reaction (SAR)	Standard: An adverse event that is both serious and, in the opinion of the reporting Investigator, believed with reasonable probability to be due to one of the trial treatments, based on the information provided.
Suspected Unexpected Serious Adverse Reaction (SUSAR)	Standard: A serious adverse reaction, the nature and severity of which is not consistent with the information about the medicinal product in question set out in the reference safety information: • in the case of a product with a marketing authorisation, this could be in the summary of product characteristics (SmPC) for that product, so long as it is being used within it's licence. If it is being used off label an assessment of the SmPCs suitability will need to be undertaken. • in the case of any other investigational medicinal product, in the investigator's brochure (IB) relating to the trial in question *Adapted: A serious adverse reaction, the nature and severity of which is not consistent with the information about the intervention in question set out in the reference safety information*

9.2 Adverse event reporting and management

9.2.1 Operational definitions for (S)AEs

These have been provided in section 9.1

9.3 Recording and reporting of AEs, SAEs, SARs AND SUSARs

All serious adverse events that are trial or treatment related will be recorded and immediately reported to the Chief Investigator and within 1 working day (24 working hours) to the ExeCTU Trial Manager. If these are also classed as unexpected they will be reported to the relevant ethics committees.

The SAE form will capture the following data:

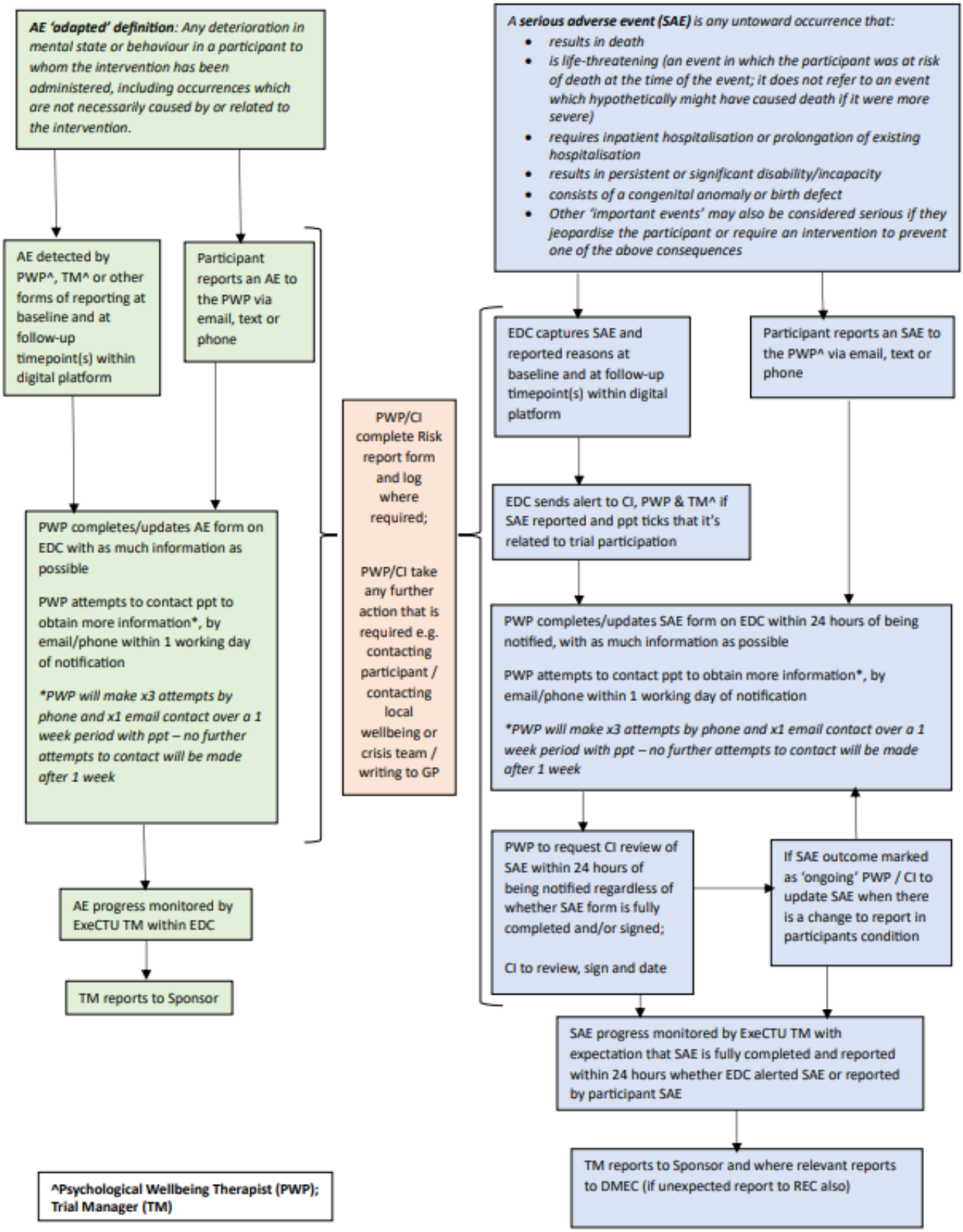
- Date and time of onset
- Date and time investigator became aware
- SAE category
    - Death i.e. (homicide, suicide, accident, illness, all appropriate options) etc.)
    - Life threatening i.e. (suicide attempt, serious assault, self- harm)
    - Hospitalisation or prolongation of existing hospitalisation or referral to crisis team
    - Persistent or significant disability or incapacity i.e. (include development of problematic substance/ alcohol abuse; onset of new Axis I disorder)
    - Congenital anomaly or birth defect
    - Other i.e. (potentially dependent life events, e.g. job loss divorce)
- The intensity will be specified as mild, moderate or severe
- The SAE will be determined as intermittent or continuous

- The SAE will be determined as expected or unexpected
- The SAE outcome will be determined as resolved with a date provided, resolved with sequelae, ongoing (follow ups to the SAE will be provided when there is a change to report in participants condition) or died (if died the cause of death will be specified)
- The SAE relationship to the study or trial procedures will be determined as not related, unlikely to be related, possibly related, definitely related or unknown
- A detailed description of the event will be provided and this field will also be used to document the dates and number of attempts made to contact a participant by phone and/or email in order to obtain details about the event, the discussion that took place during any successful phone calls/emails and subsequent actions agreed or discussed between the participant and researcher/clinician
- The CI will report on their assessment of the implications (if any) for the safety of study participants and how they will address the implications
- The form must be signed and dated by the CI

We will, in line with other complex intervention studies, monitor non-serious adverse events, serious adverse events that are not trial or treatment related, serious deterioration, and active withdrawals from treatment, with specific questions in the follow-up and in response to specific participant-initiated reports.

Symptoms of depression or anxiety will not be defined as adverse events unless suicidal ideation, plans or an attempt has been made. The reporting period for all events and reactions will be from referral to 3 month post baseline follow-up. Data on any adverse events will be collected by a member of the research team at each assessment and entered directly into the EDC.

Figure 3 Safety reporting flow chart



9.4 Responsibilities

Researchers at central site (University of Exeter) to check for SAEs, AEs and ARs when participants complete digital treatment / follow-up, potentially in response to automated feedback from website.

Chief Investigator (CI) is responsible via liaison with research team at central site for:

1. Ensuring that all SAEs are recorded in EDC and reported to the ExeCTU Trial Manager within 24 working hours / 1 working day of becoming aware of the event and provide further follow-up information as soon as available.
2. Ensuring that SAEs are chased with ExeCTU Trial Manager if a record of receipt is not received within 2 working days of initial reporting.
3. Ensuring that AEs and ARs are recorded and reported to the ExeCTU Trial Manager in line with the requirements of the protocol.
4. Immediate review of all SUSARs.
5. Review of specific SAEs and SARs in accordance with the trial risk assessment and protocol as detailed in the Trial Monitoring Plan.

Sponsor (NB where relevant these can be delegated to CI and ExeCTU trial manager)

1. Central data monitoring and verification of AEs, Ars, SAEs, SARs and SUSARs according to the trial protocol within the database (EDC).
2. Reporting safety information to the CI, delegate or independent clinical reviewer for the ongoing assessment of the risk / benefit according to the Trial Monitoring Plan.
3. Reporting safety information to the independent oversight committees identified for the trial (Data Monitoring Ethics Committee (DMEC) and / or Trial Steering Committee (TSC)) according to the Trial Monitoring Plan.
4. Reporting SAEs that are related to the trial and unexpected, by email to the research ethics committee
5. Expedited reporting of SUSARs to the Competent Authority (MHRA in UK) and REC within required timelines.
6. Notifying Investigators of SUSARs that occur within the trial.
7. Preparing standard tables and other relevant information in collaboration with the CI and ensuring timely submission to the MHRA and REC.

Data Monitoring Ethics Committee (DMEC):

In accordance with the Trial Terms of Reference for the DMEC, periodically reviewing overall safety data to determine patterns and trends of events, or to identify safety issues, which would not be apparent on an individual case basis.

9.5 Notification of deaths

All deaths will be reported to ExeCTU Trial Manager who will report to the Sponsor, irrespective of whether the death is related to the trial or an unrelated event. If the event is unrelated to the trial then this will be reported to the sponsor within one week, and if it thought to be related to the trial the report will be submitted within 2 working days.

9.6 Reporting urgent safety measures

If any urgent safety measures are taken the CI/Trial Manager shall immediately and in any event no later than 3 working days from the date the measures are taken, give written notice to the relevant ethics committee, Sponsor and other appropriate bodies where relevant of the measures taken and the circumstances giving rise to those measures.

9.7 The type and duration of the follow-up of participants after adverse reactions.

In the event of any reported adverse reaction to the intervention the participant will be contacted by the site researcher or clinician within 2 working days to review status and options.

10 STATISTICS AND DATA ANALYSIS

10.1 Sample size calculation

Sample sizes for the efficacy question are estimated based on Minimum Clinically Important Difference (MCID) for the co-primary outcomes at the primary endpoint allowing for power at 0.80 and alpha at 0.05 and using a Bonferroni correction for the 2 tests. Based on the outcomes of PHQ9 and GAD-7 over 3 months (PHQ-9, MCID 2.59, SD =5.4, GAD-7, MCID 4 points, SD=5.07) and assuming 20% follow-up attrition, the calculated sample sizes are n=129 per arm and n=41 per arm respectively.

The simplified two arm (of guided vs unguided CBT) study design and revised sample size calculation is based on providing sufficient power for both the primary and secondary objectives and in particular the need to establish robust factor estimates (modelling question).

The original sample size was based on a simple between group comparison based on a MCID and a four arm trial. However, whilst this adjusted for the multiple comparisons it did not allow for much of the necessary complexity of the analysis. In line with Luedtke A et al. Clin Psychol Sci. 2019;7(3):445-461 we have increased the sample size to 300 evaluable participants per arm. This is necessary to obtain stable estimates of factors and based on a simple between group comparison for our co-primary outcome (PHQ-9, with an MCID 2.59 and SD =5.4, GAD-7, with an MCID of 4 points and SD=5.07) adjusted for multiple testing (Bonferroni correction) with a power of greater than 99%. Allowing for a 20% loss to follow-up a sample size of 360 per group will be recruited.

10.2 Planned recruitment rate

Recruitment will take place over 26 months across 6 university sites (originally from September 2022, due to staffing issues, now potentially January 2023, updated to June 2023) to end of November 2024. This requires an average recruitment of 7.5 participants per week across all sites – prior work has indicated that we can recruit between 10-14 potential participants (eligible for one of the trials and consenting to participate) will be recruited per week, which exceeds the required recruitment rate.

10.3 Statistical analysis plan

A detailed statistical analysis plan (SAP) is to be produced; the main points of the statistical analysis are summarised here. The SAP will be approved by the TSC prior to end of participant recruitment. Any amendments to the TSC will be documented and approved by the TSC on an ongoing basis.

10.3.1 Summary of baseline data and flow of patients

The analysis and presentation of the trial will be in accordance with CONSORT guidelines (Schulz et al., 2010). Recruitment, intervention uptake, outcome completion rates and attrition will be reported (with 95% CIs) and shown on a flow diagram.

Premature discontinuation of intervention may be instigated by the participant or by an investigator. Participants may elect to withdraw from the study if they wish to do so at any time and for any reason (including perceived harms or lack of efficacy of intervention). Researchers may also request that trial intervention be discontinued for reasons of participant safety at any time; such requests will be made to and approved by the PI or an appointed deputy where possible.

Advice on a case-by-case basis may be sought from the DMEC where necessary. A participant will be withdrawn from the study entirely in the event that they are discovered to have been ineligible at the time of recruitment, in which case usual practice will continue to be provided.

As well-established digital CBT psychological interventions, we do not anticipate significant iatrogenic effects or side-effects requiring individual discontinuation. Participants who elect to discontinue their allocated intervention will be requested to continue to provide outcome data. If a participant wishes to withdraw from the study entirely (and not provide further follow-up data), they can do so without giving a reason, but we will keep any data they have already provided.

10.3.2 Primary analysis

The primary and secondary outcomes will be compared at 3-month follow-up. The primary and secondary continuous outcomes will be reported descriptively (mean and standard deviation (SD)) and inferential comparisons will be reported between the two treatment contrasts: ((1) unguided i-CBT; (2) guided i-CBT.

All analyses will be based on an intention to treat principle (i.e., according to original allocation irrespective of intervention adherence) and will include participants with complete outcome data at 3-month follow-up, and will adjust for baseline outcome score (where relevant) and stratification variables (site). Furthermore, we will adjust for any baseline participant characteristics that are substantively unbalanced at baseline (defined as a difference ≥10 percentage points across categories for a categorical variable, or a difference in means >1 SD for continuous variables), and if the characteristic is thought to be predictive of outcome. Binary outcomes (occurrence of major depressive disorder; generalized anxiety disorder) will be reported as proportions and analysed used logistic regression.

Multilevel mixed models will be used to analyse process measures and investigate mediating processes, provide insights about the types of users helped most by different types of intervention and for pre-post initiative comparisons.

All the RCTs will follow MRC Complex Interventions Guidelines and relevant CONSORT reporting requirements with a pre-registered trial protocol and use intention-to-treat as primary analysis. Randomisation will be in equal allocation (i.e., 1:1) using independent computerised randomisation, stratifying for baseline variables as relevant (e.g., gender, recruitment site). For digital RCTs, primary inferential analyses will compare trial arms across outcomes using multilevel mixed models adjusting for baseline score. Secondary analyses will include Complier Average Causal Effect analysis to estimate the effects of adherence with self-help. The extent of missing data will be considered and where necessary, in agreement with Trial Steering Committee (TSC), multiple imputation will be used. The trial statistical analysis plans will be prepared before any formal analyses and reviewed and approved by Data Monitoring Committee (DMEC) and TSC, with trial statistician and research team blinded to allocation until primary analyses are completed.

Primary analyses will use multilevel mixed-effect models, which enable us to examine nested hierarchies in the data (individual, intervention, university), across time (examining pre-to-post change), to capture dependencies in the data, to investigate individual trajectories (random intercepts, random slopes), and which have less restrictive assumptions re missing data. Statistical/methodological advice sought and provided by Exeter CTU and Prof Taylor.

Sub-project (machine-learning):

The development of machine learning models to investigate individualised treatment rules (ITRs) will be subcontracted to collaborators with expertise in machine learning, with this service costed in the grant – the collaborators will be provided with pseudonymised data linking baseline assessment with outcomes to generate composite models and run machine learning to identify predictive rules. This will be treated as a separate sub-project and will not be specified in detail in trial SAP (i.e., one paper will report main trial outcomes; separate paper will report machine learning of ITRs – that will require a further study post-grant to test if ITRs improve outcomes).

10.3.3 Secondary analyses

A number of secondary analyses will be conducted.

1. Per protocol analysis

Primary and secondary outcomes at 3 months will also be compared using a CACE analysis (‘”Compliance” being defined for all interventions as completion of a pre-specified minimum level of usage of the digital intervention (e.g., complete at least 3 modules of 6 modules in internet package) and a complier average causal effect (CACE) analysis using instrumental variable regression (Angrist et al., 1996; Dunn et al., 2005), using engagement with the intervention as the measure of adherence. These analyses will use observed data only; the CACE analysis will include participants on the same basis as the ITT analyses.

2. Imputation of missing data

Patterns of missing outcome data at follow-up will be extensively investigated. Multiple imputation models will be used to impute missing primary and secondary outcome data at all follow-up time points. Results for the between group comparisons based on these imputed data sets will be presented in addition to complete case regression analyses described above. Propensity for missingness associated with baseline characteristics will be investigated; imputation models will include treatment allocation as well as stratification variables, baseline variables, and any variables associated with missingness or included in the models as covariates due to baseline imbalance. Such imputation models are based on the assumption that missing data is ‘missing at random’, which may not be a valid assumption in this context. Nevertheless, use of imputed data will increase power if there is substantive missing data, and is the least likely method to introduce bias.

10.4 Subgroup analyses

Primary and secondary analyses will be extended to explore potential subgroup effects by including interaction terms between the intervention allocation and the stratification variables (site). Since the trial is powered to detect overall differences between the groups rather than interactions of this kind, the results of these exploratory analyses will be presented using confidence intervals, as well as a global p-value for the interaction between treatment and each variable and interpreted with due caution.

10.5 Interim analysis and criteria for the premature termination of the trial

No interim analyses are planned. In order to detect potential harms the study will monitor potential adverse effects. Adverse and serious adverse effects will be reported to TSC and DMEC who will recommend discontinuation of the trial if there is cumulative evidence that the intervention may cause harm. There are no plans to terminate the trial prematurely due to futility.

10.6 Other statistical considerations.

Comparisons will be made between all the two arms. No formal p-value adjustment will be made for multiple testing; the results of the ITT observed data analyses will be interpreted first, with the results of the additional analyses interpreted in this light. Interpretation of results will draw focus on confidence intervals rather than emphasising p-values.

Primary analyses will be performed by a statistician who remains blinded to group allocation and will be presented as such to the investigators. The results will be discussed and interpreted prior to the unblinding of group allocations. Additional analyses will then be performed following unmasking.

10.7 Mediational analyses

Mediational analyses will test the hypotheses that the digital-CBT is effective by changing unhelpful habits, increasing self-compassion, and changing cognitive and behavioural skills. Each of these potential mediators of the primary outcome is a continuous variable, assessed via the brief meditator measures across the first 8 weeks post-randomisation. For the continuous outcomes, we will use a structural equation modelling approach to evaluate the indirect (mediation) effect of the intervention via the potential mediators. We will adjust for stratification variables and baseline scores of the outcome variable, and baseline scores of the mediator variable.

For mediation analyses of longitudinal data, assuming ICC =.5, the sample sizes to achieve MCID calculated above can detect small effect sizes for mediators (β=.14) in RCTs (with up to 8 micro-repeated assessments), at power = 0.80.

A series of models will be performed for each outcome, investigating the mediation effect of each mediator variable individually, and the mediation effect of each mediator variable in an overall model combining all mediators. The mediation effect will be reported as the indirect effect of treatment via the specified mediator, with 95% confidence interval, and the proportion of the total intervention effect mediated. Analyses will include the use of instrumental variables to account for effects of unobserved confounding on mediators (Dunn et al., 2005).

11 DATA MANAGEMENT

11.1 Data collection tools and source document identification

Database management, data curation and sharing will be supported by UNEXE and Exeter CTU. Efficacy/effectiveness parameters will be directly and automatically entered into an EDC system licenced/programmed by Exeter CTU. At assessment participants will directly complete electronic questionnaires and tasks online into this EDC system and this data will be automatically processed to extract relevant anonymised parameters (from which an individual’s identity cannot be detected) and will be stored in the secure database prepared and managed by Exeter CTU.

An eCRF will be designed and set up for participants to enter data electronically by completing the website assessments designed to capture relevant pseudo-anonymised and de-identified data. Programmed and manual queries on the data completed in the eCRF will be raised centrally by UNEXE and managed by data manager– the EDC will include a reporting system so the trial team can monitor progress in recruitment, follow-up, risk and adverse events in a straightforward manner. This monitoring process of the clinical database will be done in real time throughout the course of the trial. After the database has been locked, cleaned and findings dissemination and following successful evaluation by the Steering Committee, access to the project data may be granted to other parties, following rules that will be defined in a specific agreement between the partners and third parties. Only data required for the trial will be collected.

11.2 Data handling and record keeping

There is a separate data management plan which accompanies this trial protocol which gives greater detail.

No data will be collected or used without the explicit informed consent of the participants

During the project, the team will stipulate any conclusive needs within the project regarding participants' data. This may refer to the temporariness of data storage, security of data transfer, relevant consent applications and relevant advertisement of the use of the data. In order to safeguard the confidentiality of the participants' personal information, such data will be stored in a record that will be kept locked in the institution. Only the researchers will be aware of this personal information. For research purposes each participant will be given a numerical code (to be used in place of a name). The technology should cater for the fact that each participant will be given a unique identification code, rather than a name, and all data will be securely stored and preserved, both electronically and on paper.

Only authorized research personnel will have access to the password protected electronic database. No unauthorized access will be possible. A separate list linking codes with names will be kept in a secure place. The data will be introduced and analysed by computers. As for Internet use and monitoring by means of mobile apps, data protection systems will be designed (using secure passwords, encryption, etc.). The researchers will have access to the database using a password. Also, in order to protect all information, we will follow the AES (Advanced Encryption Standard) strategies for personal password use and data encryption. The study researchers will promise to not reveal data from which personal and health information about the participants could be deduced. The same principles will be taken into consideration in the dissemination of data in the publication of scientific papers and the presentation of research reports at scientific conferences.

Database infrastructure: The project will use a distributed electronic database (managed by UNEXE, Partner 1) during the project that will store all the downloaded cohort data and clinical trial data. Within the clinical trial, UNEXE will be in charge of the set-up and management of the database. The equivalent of anonymised electronic Case Report Form (eCRF) data will be set-up and entered in a data management system, which is fully validated. The eCRF and associated database will be automatically populated from the responses entered by participants via websites and app platform: data will be encrypted and anonymised before downloading from the website or app and then stored securely and converted into an electronic database suitable for analysis. A data manager will be appointed to build and manage the database infrastructure. Data will be routinely backed-up during and after the project to ensure the availability of all the information.

Data Management Plan: The Data Management Plan will describe how the data will be exploited, checked, shared, curated, and preserved. Thus, the procedure for granting access will be detailed and

the mechanisms to access the data after the project will be described. The ownership of data generated during the project will be described in the Consortium Agreement.

Data format and types: Standard data formats will be used during the project and will be compliant with Clinical Data Interchange Standards Consortium - Clinical Data Acquisition Standards Harmonisation (CDISC-CDASH) standard. Data types will include Volunteer data: Demographics, information provided by participants on questionnaires and on EC assessment instruments.

Data exploitation: All information will have a digital format that will be handled in accordance with national data protection regulations. A mechanism to request access, mine, exploit, reproduce or disseminate data generated in the framework of this project will be put in place. After successful evaluation by the consortium, access to the project data may be granted to other parties, following rules that will be defined in a specific agreement between the partners and third parties.

11.3 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution and the regulatory authorities to permit trial-related monitoring, audits, and inspections- in line with participant consent.

11.4 Archiving

Source documents, and trial-related electronic and other data will be stored safely and in accordance with the requirements of the UKGDPR and Data Protection Act (1998), no longer than legally required (for a minimum of ten years) or as stipulated by the Sponsor's requirements, and the applicable regulations and as per the Clinical Trial Units existing Business Continuity, Disaster Recovery & Archiving Standard Operating Procedures.

Data Access: Post-analysis, the final anonymised dataset will preferentially be stored in Open Research Exeter (ORE), the University of Exeter's open access repository.

Interoperability: Source data will be stored in Microsoft SQL server, formatted to maximise fidelity. This can be transposed and converted during the analysis stage into any format required. For the Open Research Exeter repository XML or CSV with a separate data dictionary is recommended.

Archiving: Items submitted to ORE will be retained indefinitely. ORE content is securely held on University of Exeter servers and regularly backed up according to current best practice. The ORE team will also try to ensure continued readability and accessibility of content, including the migration to new file formats where necessary.

Data archiving is described in further detail within the Data Management Plan.

11.5 Authorisation of participating sites

The trial will be conducted and managed directly from the University of Exeter and CTU – with other institutions only used to advertise the trial to aid recruitment of participants, as such each site may not need their own site-specific ethics, and there may be no requirement for data transfer between Exeter and the recruitment sites.

12 MONITORING, AUDIT & INSPECTION

Monitoring and vigilance activities

UNEXE will perform a risk assessment and base a monitoring plan on this risk assessment. UNEXE will assign a data manager to this role, who will provide monitoring of recruitment, retention, and adverse events and management of the centralised recruitment and data management systems, and support and evaluate the quality and integrity of study operating procedures and protocol adherence to applicable regulations. Additionally, the trial manager will manage study progress by tracking ethics submissions and approvals, recruitment and enrolment, data completion, and data queries (generation and resolution).

Central vigilance and the reporting of Serious Adverse Events (SAEs) will be provided by UNEXE (Part. 1) following good safety practice. A SAE-Form will be available to the project team to complete as necessary. Safety and tolerability will be evaluated by recording AEs and SAEs throughout the study.

Quality assurance procedures for the Clinical Trial

The appropriate design of a clinical trial protocol ensures the safety, rights, and well-being of participating patients. The clinical protocols for the trial will be finalised after being reviewed and approved by the UNEXE ethics board. International Conference on Harmonisation and Good Clinical Practice quality standards and Standard Operating Procedures will be set-up including case documentation, data collection, monitoring, validation, evaluation, archiving and reporting of adverse events, with support from the UNEXE Clinical Trial Unit. This includes finalising the trial protocol and registration of the trial and publication of the trial protocol.

The Sponsor will be responsible for the development of the essential trial documentation delegated to the Exeter CTU and the trial manager (located in the CTU) such as electronic Case Report Form (eCRF) and documents related to monitoring (initiation, monitoring and close-out visit reports). This includes the development of a specific data management plan for the trial, starting with an initial data management plan that provides a generic overview of how to make the data findable, accessible, interoperable, and reusable, including the handling of data during and after the project, which data will be collected, processed and generated, the methodology and standards applied, and plans for data sharing, data curation and data preservation.

UNEXE will have overall responsibility for the monitoring of the delivery of the clinical studies across the internet website, EDC and internet delivered treatment and will therefore employ a trial manager, who will provide monitoring checks and site management, evaluate the quality and integrity of study sites practices and protocol adherence to applicable regulations, and manage the progress by tracking regulatory submissions and approvals, recruitment and enrolment, data entry, data management, data completion, data queries (generation and resolution). This process will be automated through the use of the EDC system as primary point of access to study and to collect data, provide intervention and monitor outcomes. The trial manager at UNEXE will check and coordinate this process.

13 ETHICAL AND REGULATORY CONSIDERATIONS

The research activities of this project include: Collection and processing of personal data, including sensitive personal data (i.e. health), and tracking of participant's mood, symptoms and well-being over time; - Intervention programme (the selected participants undergo guided digital transdiagnostic CBT); Control (selected participants undergo unguided digital transdiagnostic CBT).

We note the urgent need to conduct research in young people in order to overcome equipoise and establish the evidence base for selecting the relevant treatment for young people.

Key ethical issues are (a) individual autonomy entailing the giving of free and informed consent and respect for privacy and confidentiality of personal data;

(b) the safety and wellbeing of participants.

To address (a), participation will be free and voluntary; electronically-signed informed consent will be obtained from each participant prior to entering each study; all research data will be pseudonymously recorded using identification numbers rather than contact details (name, email) to assure participant confidentiality in numerical databases. All information collected in this study will be kept confidential, except as required by law. Data will be obtained and stored in line with GDPR requirements, using secure university servers/cloud-based systems.

With respect to (b) there is no known health risk associated with any of the assessments or initiatives proposed. We anticipate that digital CBT will improve wellbeing. Nonetheless, we will assess for potential harms. Project researchers will be trained in and provided with a protocol to safeguard students, assess and manage risk, including referral to local student university Mental Health service, and access to a designated Mental Health clinician to support them. The initial screening process for RCTs will exclude anyone with a history of psychosis or bipolar disorder and those reporting elevated suicidality and automatically signpost these individuals towards appropriate guidance and help, including general information on the presenting symptom, recommended actions to keep themselves safe, advice to seek medical help from GP, direct links to relevant national sources of help, and the option to request that the respective university support services contact the individual.

For participants consented into surveys or studies who report risk (e.g., suicidal thoughts) or significant/worsening symptoms on outcome measures on the screening or follow-up websites, the same automatic messaging re recommended actions and signposting is provided plus participants continue in the study and can contact a site researcher via e-mail or telephone to seek advice. This procedure has been successfully used in prior student studies, received ethical approval, and agreed in partnership with university mental health services and Student Guild welfare representatives. Similar in-person safeguarding procedures will be used to support student partners as necessary.

13.1 Research Ethics Committee (REC) review & reports

Ethical considerations have been taken into account from the design of the study, to the conduct and to the reporting of study results.

The investigator will supply all necessary information to the sponsor for submission of the protocols and consent forms to the national competent regulatory (local Ethic Research Committee), to the UNEXE IRB and to the national authorities for the data protection for review and approval and for the registration in clinical databases.

Research will only start after obtaining approval from the local Ethic Research committee and IRB. The local Ethic Research Committee and IRB will only approve a specific research proposal.

Participation will be free and voluntary and electronically-signed informed consent will be obtained from each participant prior to entering the study. Because the project is principally conducted through digital medium (website and apps), information sheets and consent forms will be provided through these medium and participants will be able to signify their consent electronically. All data will be anonymously recorded using specific Case Report Forms (CRFs) to assure participant confidentiality in numerical databases, as required by personal data protection laws. Quality assurance will be assured by the organisation of monitoring (via the EXECTU website) and control of CRFs to evaluate the progress of the study, verify the accuracy and completeness of data and assure that all protocol requirements, applicable local laws and GPC/ICH guidelines are respected. At the end of the study, according to GPC/ICH guidelines, the closure of the study will be checked. All data analyses and CRFs will be archived in Exeter according to the local regulation.

All procedures at the very least comply with international guidelines and with current national legislation. The project will only start after approval of the corresponding local ethical committee.

All information collected in this study will be kept confidential, except as permitted by law. Data obtained for this research study will be accessible only for the researchers directly involved in this study. If any publication or presentations results from this research, the participants will not be identified by name or other potentially identifying information.

This project involves human data collection and processing of personal data. No physical injury, financial, social or legal harm will be directly posed to the participants, and potential psychological risks will not exceed the daily life standard. The PIs at each site and have extensive experience with handling and collection of data of this type for research purposes.

The main ethical issues for the clinical trials are ensuring:

(i) Understanding and voluntary written/electronic informed consent from all participants;

(ii) Participant confidentiality and anonymity;

(iii) The safety and well-being of participants.

The study investigators will conduct the clinical study in adherence to the fundamental ethical principles of respect for human dignity, non-exploitation, non-discrimination and non-instrumentalisation. The following principles will also be adhered to:

- Individual autonomy (entailing the giving of free and informed consent, and respect for privacy and confidentiality of personal data)
- Justice and the principle of beneficence and non-maleficence (namely with regard to the improvement and protection of health)
- Proportionality (including that research methods are necessary to the aims pursued and that no alternative more acceptable methods are available).

Before the start of the trial, approval will be sought from a REC for the trial protocol, informed consent forms and other relevant documents e.g., advertisements and GP information letters. Ethical approval will be sought from the REC of the University of Exeter.

In either case the following principles will be upheld:

- substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the trial
- all correspondence with the REC will be retained in the Trial Master File/Investigator Site File
- the Chief Investigator will notify the REC of the end of the trial
- if the trial is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination
- within one year after the end of the trial, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC

13.2 Peer review

The project received favourable review from the UKRI Medical Research Council for grant award.

13.3 Public and Patient Involvement

Student Advisory Group (SAG)

In order the maximise the quality and benefits realised from the project and its outputs, the role of end users will be emphasised and a co-design approach will be adopted by including young persons in decision-making. For this, we are creating a Student Advisory Group, which will advise us on all aspects of the overall project. Roles for the SAG include:

- Help to steer, guide, and shape the project as it unfolds.
- Help the project access the full spectrum of students, to achieve diversity and representation in those who take part.
- Provide representation into project decision-making and governance (Steering committee; Independent Advisory board)
- Develop branding and engagement strategy to maximise student involvement.
- Develop, co-design, and consult on adapting research materials, surveys, interventions and wellbeing tools.
- Help to publicise findings and outputs and to support the dissemination to students and active implementation into universities of evidence-based approaches

The Group consists of undergraduate and postgraduate students at the Universities of Exeter, Cardiff, Oxford, Southampton, Newcastle, and King’s College London

The SAG will meet ahead of key decisions making points in the wider Nurture-U project in order to make the most of this resource.

Students (e.g., via Student Advisory Board) will advise and have input to the wording and content of the information sheet and informed consent form to ensure simple, clear, comprehensive, and meaningful for the target population.

13. 4 Trial management responsibilities

A dedicated trial manager will assist in the day-to-day management of the project, coordinate recruitment and retention, and will be responsible for effective communication and monitoring progress. The trial will be managed by a core research team who will meet weekly. There will be a Cohort Trial Senior Management group, who will meet by teleconference or video-conference on a bi-monthly basis to review progress and set targets. The trial manager will be mentored by an EXCTU senior manager. The trial will be registered with www.controlledtrials.com or other recognised international trial registration sites and assigned an ISRCTN number. Researchers will be trained in Good Clinical Practice. We will comply with the UK Department of Health Research Governance Framework for Health and Social Care. The trial will be conducted to protect the human rights and dignity of participants as reflected in the 1996 version of Helsinki declaration. Trial documents will be retained for a period of 10 years after the completion of the study as detailed in the Patient Information Sheet.

13.5 Regulatory Compliance

The trial will not commence until a Favourable REC opinion is obtained.

13.6 Protocol compliance

Prospective, planned deviations or waivers to the protocol are not allowed under the UK regulations on Clinical Trials. The trial team will take all efforts to prevent and monitor any deviations so that they will not be used, e.g., it is not acceptable to enrol a participant if they do not meet the eligibility criteria or restrictions specified in the trial protocol

Accidental protocol deviations will be adequately documented on a relevant protocol form and reported to the Chief Investigator, Sponsor, and TSC within 2 working days.

The trial team recognises that deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

Participants are told who will be excluded from taking part in the trial on the introductory pages of the CTU screener. This is so that they know if they would be excluded before they take part in the screening and can choose not to take part in the assessment, rather than be excluded.

All advertising will also only be targeted at those meeting the relevant criteria. This is possible by setting online adverts to only those of the specified age group and residency and associated with particular universities (e.g., geographic location) promoting recruitment where only this age group study, work or enjoy leisure activities. There will be no recruitment through any NHS services.

Should it be identified that a participant taking part was recruited in error (would have met the exclusion criteria) then this will be recorded as a protocol violation. A log of all protocol violations will be kept and protocol violations will be reported to the chief investigator and the sponsor within one working day.

13.7 Notification of Serious Breaches to GCP and/or the protocol

The log of protocol violations and any SAE’s will be considered and monitored by both the sponsor and the TSC. If the sponsor and/or the Steering Committee consider that there is any significant danger to

the participants of the trial or a reduction in the scientific value of the trial then this will be discussed with the ethics committee within 7 days.

13.8 Data protection and patient confidentiality

Data protection

The conduct of the project will comply with GDPR. Adequate measures to ensure data protection and confidentiality will be duly taken into account by the project team. Local and national rules on data protection will be followed and no personal information of participants will be transferred unless such transfer is essential for the conduct of the trial.

A privacy impact assessment (data protection impact assessment) will be carried out if requested by the funder, ethics committee or sponsor. If one is carried out it will be conducted according to the guidelines of the UK Information Commissioners Office: Conducting privacy impact assessments code of practice, Information Commissioner's Office (ICO), 2014.

https://ico.org.uk/media/fororganisations/documents/1595/pia-code-of-practice.pdf.

Data will be stored in separate databases that are linked by the unique identifier ID to pseudonymize all information collected. The first database contains information related to informed consent and information enabling researchers to directly contact participants. On the screening website, participants are not asked to provide their name or any contact details until they have been provided with the participant information sheet and privacy policy. At the point of asking participants to consent to take part in the assessment, they are asked for their name, email address and phone number. The second database contains all the baseline and follow up data collected from the EDC system. A third database will store all data collected as part of the project directly from the internet CBT treatment. The codes linking contact information with the databases containing outcome will be destroyed as early as is legally required (no earlier than all data being archived) – data (including participant details and consent) may need to be retained and not deleted for a longer period due to future research indicators that may require researchers to contact the individual or actions taken by participant against the research. This approach has proven successful in prior digital interventions for well-being and been approved by multiple institutional and National Health Service research ethics in the UK; adaptations will be made as necessary for specific local ethical requirements.

The Exeter research team will have access to the database that connects the ID number to a person and their full contact details. This is so that they can contact the participant if they report technical difficulties, if any suicide risk is indicated, and to send reminders regarding assessments. Email and text for reminders will never contain personal or other information about the collected data, but remind participants, in a general manner, about open tasks. Exeter Nurture-U researchers, clinicians and the chief investigator only will be set up with a username and password to access the CTU database that stores the personal data. The researchers are not given the allocation details so as to maintain blind.

Digital Information:

Files containing digital information must be encrypted with password-protection where appropriate and stored on a secure network (not a local 'C') drive. Where local copies are required for processing or transfer preparation, it should be ensured that the target workstation is compliant with all host organisation security policies and that they are followed in use. This is particularly important for laptops/netbooks/portable workstations, especially about encryption and should be confirmed by the host organisation before transferring data. The relevant university guidelines and policies will be followed (e.g., for the University of Exeter, the University Information Security Policy, and the University Computing Regulations - a copy of the specific University guidelines for portable devices is available here: http://alf.exeter.ac.uk/share/s/GwluvMWoQn-_FPAwNFxS7g. Participants identifiable data must not be stored on home computers, personal laptops, unencrypted memory sticks, CDs, handheld devices, digital cameras or other imaging equipment even if they are password protected. An encrypted memory stick may be used if required.

All data generated will be stored by University of Exeter in encrypted and password-locked files behind a secured firewall operating within a university environment with state-of-the-art safety protection measures, and transmission of information via electronic means will be performed using encrypted data files. The exact process for data storage and encryption for the data processors will be directed by the data controller and outlined in the data management plan.

Participant data:

Participant confidentiality and welfare will always be maintained as the highest priority. Anyone with access to data, including the investigators, is subject to professional secrecy during and after the trial. Collaborators outside of Exeter will only be given access to de-identified data, and they must sign a declaration stating that they will adhere to UK data protection legislation. We plan to use the standard contract for transfer of personal data. We do not anticipate any sharing of data from this clinical trial with sites outside of the EU during the course of the project.

Anonymised data (health information, socio-demographic information, platform usage information) will not be deleted until the completion of the scientific analysis of the data plus the mandatory period for retaining clinical data (at least ten years in the UK).

Responsibility:

The University of Exeter as sponsor of the trial is the data controller. The controller has the responsibility to ensure that the security and access arrangements for the database comply with the Data Protection Act (1998), and that all data processing and locally held personal data are registered with the host institution according to their employer's processes. Because this trial involves the processing of personal information the Information Commissioner's Office (ICO), will be notified accordingly.

Legal data transfer agreements will be written and signed between the data controller and data processors prior to any participant being recruited, where appropriate. These agreements will be confirmation that the data processors will adhere to GDPR regulations, which protect and safely store participant personal and outcome data.

A common data protection and privacy policy authorised by the sponsor and the University of Exeter data protection team will be available on the study website. The screening website will also email this policy to consenting participants with the information sheet and consent form or provide it as a download.

Transfer of data to consortium researchers:

All data transfers must be approved by the Trial Management Team and must be logged and accompanied by a Data Transfer Form: signed by the CTU staff member transferring the data, consistent with data protection legislation and the responsibility of University of Exeter as the data controller. Outcome data will be extracted from the database (usually SPSS or STATA format), on a routine basis and prior to per protocol analysis, to be made available to the project statistician in a secured manner (encrypted files via ftps/https servers). University of Exeter will be responsible for collecting all data and analysing it for the trial so it is unlikely that Exeter will be sending data to other sites.

Data Monitoring:

Data will be accessed by the trial manager / data manager on the EXCTU data base on a regular basis (typically at least weekly) to check recruitment numbers and data quality and to monitor that all processes are working correctly. Detailed checks will occur early in the project to confirm that all systems are working properly. To download data the trial manager has to login via user name and password.

Breach of confidentiality:

Occasionally records containing personal data that should not have been disclosed, e.g. an e-mail with a data file containing identifiable details may be received by a member of CTU staff or another staff member from an internal or external source. In such situations, the member of staff should contact the person who sent the data and make them aware of the breach of confidentiality. The records received should be either promptly deleted or any identifying details thoroughly erased. All suspected breaches

should be investigated, documented in the study file and reported to the Sponsor as appropriate, following an established data breach the UNEXE procedure will be followed.

13.9 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall trial management

To our knowledge, the chief investigator, PIs at each site and committee members for the overall trial management have no financial and other competing interests for the trial management. At regular intervals (6-monthly), trial management and Trial Steering Committee will be asked to declare if any financial or other competing interests.

13.10 Indemnity

The University of Exeter will have insurance cover place to cover the legal liability for any illness or injury to a participant of the trial arising from participating in the trial.

13.11 Amendments

Changes to the protocol should only be made via an approved protocol amendment. Protocol amendments must be approved by the sponsor and the local Ethic Research Committee prior to implementation, except when necessary to eliminate hazards and/or protect the safety, rights or welfare of subjects.

13.12 Post trial care

Medical care is not being provided in this trial so will not be provided after the trial. It is expected that the interventions will be used for at least one to three-month period following randomisation.

13.13 Access to the final trial dataset

At the end of the trial, collaborators will be able to request copies of the anonymised data from Exeter CTU. Who is able to access which data will be decided by the steering group.

14 DISSEMINATION POLICY

14.1 Dissemination policy

There is an overall dissemination policy for the project, within which there is a specific dissemination policy for the trial results.

Key aspects of the dissemination policy for the trial include:

(i) the Consort Guidelines and checklist are reviewed prior to generating any publications for the trial to ensure they meet the standards required for submission to high quality peer reviewed journals etc. http://www.consort-statement.org/

(ii) Anonymised data arising from the trial is owned by UNEXE as trial lead, lead for trial design, CTU, and trial analysis, and developer of the intervention, managed by UNEXE as the data controller.

(iii) On completion of the trial, the data will be analysed and tabulated and a Final Trial Report prepared, and made publicly available on the trial website and via the funder. This will be published before the end of the grant.

(iv) Our publication policy stipulates that all potential publication plans need to be reviewed by the Project Steering Committee before release of data to coordinate activity between partners, determine appropriate authorship and avoid duplication and replication of effort.

(v) Authorship will be determined on standard criteria (i.e., consistent with the criteria for individually named authors or group authorship such as The International Committee of Medical Journal Editors defined authorship criteria for manuscripts submitted for publication http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html#two) and will require contributions with respect to design of the study, development of paradigms and interventions within the study, involvement in delivery of the trial, data analysis and/or writing up of the paper. Seniority of authorship will be determined by relative contribution on these elements – individuals leading on design, analysis and write-up of papers will have lead authorship, with this typically following pre-allocated lead roles for the work packages in the grant in the first instance, unless deferred. All papers will include a detailed statement of the relevant author contributions following a standard template.

(vi) All publications as well as all tools described in this section will acknowledge funding from the UKRI Adolescence, Developing mind and Mental Health scheme.

(vii) There are plans to notify the participants of the outcome of the trial, through a combination of a specifically designed newsletter, blog, vlog, videos and website, communicated to participants via email and relevant social media on completion of the study.

(viii) It is possible for the participant to specifically request results from their PI and this information be provided after the results had been published.

(ix) The trial protocol, full trial report, anonymised participant level dataset, and statistical code for generating the results will be made publicly available.

15 REFERENCES

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16 APPENDICES

Appendix A:
Risk Assessment and Reporting: automated feedback during assessments

In the assessments we explicitly ask and screen for symptoms of distress, wellbeing, and poor mental health (including symptoms of depression, suicidal risk, prior diagnosis by a clinician as self-reported by user of depression, mania or psychosis, and antidepressant use). Whether meeting exclusion criteria at baseline or indicating risk at follow up, participants will be provided with automatic feedback with suggested sources of help such as the recommendation to consult their GP or weblinks or phone numbers for national services.

Pre-screening

A pre-screening section links to our website to allow those with experience of, or symptoms of depression to access help pages linking to sources of support as soon as possible.

In Trial

For those taking part in the trial there is the option for seeking more information from the study team and where risk is indicated a trial clinician may contact them directly.

Each occurrence of risk will be logged by the electronic system and the relevant research officer informed.

We note that the nature of the high level of confidentiality means that we do not necessarily have relevant GP or family doctor details for participants, unless these are provided voluntarily in additional communications, and thus of the main management pathways for detecting a clinical presentation, the default response is direct information disclosure to the participant of a potential clinical issue with appropriate advice and signposting. Nonetheless, when we alert a student that they are having symptoms consistent with clinical cut-offs the clinician can offer to contact their primary care doctor on their behalf if they volunteer the necessary contact information.

The third option (“right not to know”) is not deemed appropriate in this context when applied to the individual young person: since the likeliest presentation (elevated symptoms of depression, distress and stress) is treatable. Based on recent recommendations, our default policy is to inform young people of the possibility of them having these conditions and to recommend they seek help. This is to prioritize their welfare.

Preventing abuse of participants and risk analysis

Our risk analysis indicates potential theoretical risks and opportunities for abuse of the research findings and of participants within the study including psychological harms (e.g., distress), invasion of privacy (e.g., intrusion into private affairs, public disclosure of embarrassing private information, publicity that puts the individual in a false light to the public, or appropriation of an individual’s name or picture for personal/ commercial advantage), loss of confidentiality (personal data becoming public through error or thorough deliberate hacking), and social harms (e.g., embarrassment, stigmatization). The risk analysis indicates that the likelihood of these risks occurring is relatively low although any potential impact for participants would be high, and, as such, we will enact a detailed participant risk register and update it regularly through the project. Multiple steps and processes will be put into place to mitigate and minimise these risks including (a) explaining potential risks in the information sheet; (b) the welfare procedures described above to minimise participant distress; (c) high levels of security and the use of privacy by design protocols for the app and database; (d) a privacy impact assessment; (e) the emphasis on confidentiality in the project and the separation of collected data from personal identifiers; (f) the use of a code of conduct for all researchers.

Participants will be offered therapy for depression/anxiety with or without support. Participation in the study does not include routine contact with GP’s or other medical practitioners. Participants are advised

of this on the information sheets and sign the section on the consent form to confirm that they understand this.

Identifying Suicide Risk

These are 3 ways that a recruit or participant could indicate risk to the research team either during a screening/follow-up assessment, or in direct contact with a trial researcher by phone, text or email or in communication with the trial therapist in the guided treatment arm (or by conversation with therapist/administrator in unguided treatment arm)

1) **EDC Website at Screening**

A recruit may indicate risk on website during the screening assessment in response to questions about suicidality. If the participant scores 1-3 on question 9 of the PHQ9, then further questions to assess risk will automatically be presented;

PHQ9Q9

Over the last two weeks, how often have you been bothered by any of the following problems? Thoughts that you would be better off dead, or of hurting yourself in some way?

Those scores would represent the answers several days (1), more than half the days (2) and nearly every day (3)

The further risk questions which will automatically be asked:

R1 In the last 2 weeks have you been experiencing regular thoughts about suicide?

R2 In the last 2 weeks have you had any intention to hurt or kill yourself?

R3 In the last 2 weeks have you made any plans to harm yourself or end your life?

If score includes PHQ9 -Q9>= 2 and yes to R2 or R3 at screening excluded from trial and signposted to relevant help re suicidality re automatically presented with the following risk page:

“Your responses to these questions suggest you have been thinking about suicide or about hurting yourself.

These kinds of thoughts can vary a lot. This may have just been a brief passing thought or reflect a sense of feeling trapped, but without any intention to do anything. These thoughts are relatively common and not that unusual in people who feel stressed. If you would like support with these thoughts, please contact your GP or relevant medical professional.

If you feel at high risk to yourself or others, please contact your GP immediately.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

However, you may have been thinking about your death a lot, having persistent thoughts about killing yourself, experiencing suicidal intentions and urges, or be making plans to end your life. In any of these cases or if you have any other thoughts of suicide, we strongly recommend that you contact your general practitioner or family doctor **RIGHT AWAY** for advice and tell them how you are feeling

If you don't think you can stay safe, please go to the nearest hospital accident and emergency room. If none of these options are available, please contact a family member or a trusted friend, so that you won't be alone right now. It's important to seek out the company of people who can support you and who will help to keep you safe.

Try to commit to a plan of action that does not involve suicide. If you have items that maybe dangerous for you at home, please consider giving them to a trusted friend, neighbour, the police or a pharmacist for safe keeping until you feel stronger. Try to minimise the use of alcohol or illicit drugs, as using these substances are likely to make your recovery harder. It can also be helpful to think about your faith, loved ones, family and pets. It is important to remember that these feelings and urges do pass, and when individuals feel better, they are glad that they did not act on them. There are effective treatments that can help, and there is no need to struggle alone. Talking to people who understand can make it much easier to manage your symptoms so do please call one of the specialist helplines above. There may be reasons for hope that you have yet to consider. Sometimes the smallest reasons for living can get you through a difficult time. Having thoughts of suicide is nothing to be ashamed of and we encourage you to seek help.

Because the study is focused on promoting mental health and preventing poor mental health in the future, rather than treating current difficulties, this study is not suitable for you. The unguided internet treatment has not been designed to help with these difficulties so we are sorry to say that taking part in the study would not be in your best interests at this time. Thank you for your interest.

We strongly recommend contacting your GP or family doctor as the best person to decide what help you need.

IN AN EMERGENCY – SUICIDAL THOUGHTS
If you are experiencing suicidal thoughts and think that you might be unable to keep yourself safe, visit your nearest Accident and Emergency department or call 999.

University Based Support

GP: Book an appointment with your GP. They can offer advice or refer you to other more specific services to get help. You can register with an external medical practice if you prefer.

University specific support:

- For students at the University of Exeter, there are a wide range of wellbeing and support services - https://www.exeter.ac.uk/students/wellbeing/
- For students at the University of Cardiff, there are a wide range of wellbeing and support services - https://www.cardiff.ac.uk/study/student-life/student-support
- For students at the University of Oxford, there are a wide range of wellbeing and support services - https://www.ox.ac.uk/students/welfare
- For students at the University of Southampton, there are a wide range of wellbeing and support services – https://www.southampton.ac.uk/studentservices/support-wellbeing.page
- For students at Newcastle University, there are a wide range of wellbeing and support services – https://www.ncl.ac.uk/wellbeing/
- For students at King's College London, there are a wide range of wellbeing and support services - https://www.kcl.ac.uk/wellbeing

In addition to your GP or if you don't feel that you can talk to your GP, there are many useful services and useful sources of support.

We hope that you find one or more of the following helpful:

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org
- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours) offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org

1. **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
2. **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk

- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk
- There are a series of NHS self-help guides which can be found here https://web.ntw.nhs.uk/selfhelp/
- There are more guides and online courses here: https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

If you would like further advice on these issues from the team, you can contact us by submitting the form below to send an email to the research team.

We note that the research team are not clinicians and cannot provide therapy. However, we can guide you in accessing help, for example, by contacting your GP, which is why we ask for GP details. The team are only available during normal working hours, Monday to Friday and may take 1 or 2 working days to respond.

FORM TO SUBMIT

Name

Address

Phone number

GP Name

GP Phone number

GP Address

2) <u>Assessment Website at Follow-up (3 months)</u>

A recruit may indicate risk on the assessment website in follow-up assessments in response to questions about suicidality. If the participant scores 1-3 on question 9 of the PHQ9, then further questions to assess risk will automatically be presented:

PHQ9Q9

Over the last two weeks, how often have you been bothered by any of the following problems? Thoughts that you would be better off dead, or of hurting yourself in some way?

Those scores would represent the answers several days (1), more than half the days (2) and nearly every day (3)

The further risk questions which will automatically be asked:

R1 In the last 2 weeks have you been experiencing regular thoughts about suicide?

R2 In the last 2 weeks have you had any intention to hurt or kill yourself?

R3 In the last 2 weeks have you made any plans to harm yourself or end your life?

If the recruit answers yes to any of those questions, then they would continue in the trial and would be automatically presented with the following risk page:

"Your responses to these questions suggest you have been thinking about suicide or about hurting yourself.

These kinds of thoughts can vary a lot. This may have just been a brief passing thought or reflect a sense of feeling trapped, but without any intention to do anything. These thoughts are relatively common and not that unusual in people who feel stressed. If you would like support with these thoughts, please contact your GP or relevant medical professional;

If you feel at high risk to yourself or others, please contact your GP immediately.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

However, you may have been thinking about your death a lot, having persistent thoughts about killing yourself, experiencing suicidal intentions and urges, or be making plans to end your life. In any of these cases or if you have any other thoughts of suicide, we strongly recommend that you contact your general practitioner or family doctor RIGHT AWAY for advice and tell them how you are feeling

If you don't think you can stay safe, please go to the nearest hospital accident and emergency room. If none of these options are available, please contact a family member or a trusted friend, so that you won't be alone right now. It's important to seek out the company of people who can support you and who will help to keep you safe.

Try to commit to a plan of action that does not involve suicide. If you have items that maybe dangerous for you at home, please consider giving them to a trusted friend, neighbour, the police or a pharmacist for safe keeping until you feel stronger. Try to minimise the use of alcohol or illicit drugs, as using these

substances are likely to make your recovery harder. It can also be helpful to think about your faith, loved ones, family and pets. It is important to remember that these feelings and urges do pass, and when individuals feel better, they are glad that they did not act on them. There are effective treatments that can help, and there is no need to struggle alone. Talking to people who understand can make it much easier to manage your symptoms so do please call one of the specialist helplines above. There may be reasons for hope that you have yet to consider. Sometimes the smallest reasons for living can get you through a difficult time. Having thoughts of suicide is nothing to be ashamed of and we encourage you to seek help.

We strongly recommend contacting your GP or family doctor as the best person to decide what help you need.

In addition to your GP or if you don't feel that you can talk to your GP, there are many useful services and useful sources of support.

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If you are experiencing suicidal thoughts and think that you might be unable to keep yourself safe, visit your nearest Accident and Emergency department or call 999.

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GP: Book an appointment with your GP. They can offer advice or refer you to other more specific services to get help. You can register with an external medical practice if you prefer.

University specific support:

- For students at the University of Exeter, there are a wide range of wellbeing and support services - https://www.exeter.ac.uk/students/wellbeing/
- For students at the University of Cardiff, there are a wide range of wellbeing and support services - https://www.cardiff.ac.uk/study/student-life/student-support
- For students at the University of Oxford, there are a wide range of wellbeing and support services - https://www.ox.ac.uk/students/welfare
- For students at the University of Southampton, there are a wide range of wellbeing and support services – https://www.southampton.ac.uk/studentservices/support-wellbeing.page
- For students at Newcastle University, there are a wide range of wellbeing and support services – https://www.ncl.ac.uk/wellbeing/
- For students at King's College London, there are a wide range of wellbeing and support services - https://www.kcl.ac.uk/wellbeing

We hope that you find one or more of the following helpful:

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org
- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org

3. **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
4. **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk

- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

If you would like further advice on these issues from the team, you can contact us by submitting the form below to send an email.

We note that the research team are not clinicians and cannot provide therapy. However, we can guide you in accessing help, for example, by contacting your GP, which is why we ask for GP details. The team are only available during normal working hours, Monday to Friday and may take 1 or 2 working days to respond.

FORM TO SUBMIT

Name

Address

Phone number

GP Name

GP Phone number

GP Address

In the event that a participant indicates suicide risk at follow up and this screen is displayed, an automated report/record from the website will be sent to the therapists and chief investigator and logged by them and the trial manager. The record will show the trial number and the answers to the 3 risk questions (e.g., R1=Y, R2=N, R3=N). This data will monitor frequency of suicidality across the trial arms.

3) Significant levels of depression at follow-up assessments

For participants reporting significant levels of depression at any of the follow-up assessments (defined as PHQ-9 score >20), the follow-up website will automatically provide them with the following information:

"Your responses to these questions suggest that within the last month, your overall mood has been low for at least 2 weeks and has had a negative effect on your life. It may be that you are currently experiencing an episode of depression or going through a period of stress or loss.

If you currently are having problems with the symptoms of depression then **we strongly recommend that you talk to your general practitioner, family doctor or a mental health professional** about your difficulties, as he or she may be able to find ways to help you to improve your mood and handle life's difficulties better.

If you have not had a health check recently that may also be worth doing so. If you have a diagnosis of depression, please make sure that you follow your treatment regime and consult with the medical professionals involved in your care.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

As well as your GP, there are many other services available who are really experienced at helping people with your symptoms:

University specific support:

- For students at the University of Exeter, there are a wide range of wellbeing and support services - https://www.exeter.ac.uk/students/wellbeing/
- For students at the University of Cardiff, there are a wide range of wellbeing and support services - https://www.cardiff.ac.uk/study/student-life/student-support
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- For students at King's College London, there are a wide range of wellbeing and support services - https://www.kcl.ac.uk/wellbeing

Here are some useful websites that you access directly:

- **Students against depression** is a website by students, for students offering information, guidance and resources to those affected by low mood, depression and suicidal thinking. Alongside clinically-validated information and resources it presents the experiences, strategies and advice of students themselves – after all, who better to speak to their peers about how depression can be overcome? https://www.studentsagainstdepression.org/
- **YoungMinds** are there to make sure all young people get the best possible mental health support and have the resilience to overcome life's difficulties. They provide lots of resources to help with young person's mental health: https://youngminds.org.uk/find-help/

- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/
    - **For info about depression:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/depression/#.XGQRn1X7SUk
    - **For apps to help with your mental health and wellbeing:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
- **Rethink Mental Illness** Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
    - Toolkit for young people with questions or worries about their mental health: https://www.rethink.org/media/1020652/ResourceFinal.pdf

  There are a series of NHS self-help guides which can be found here https://web.ntw.nhs.uk/selfhelp/
- **There are more guides and online courses here:** https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

Helplines

Alternatively, here are helplines you can ring to talk to someone about what you're going through:

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org

- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org

5. **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
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- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**.

4) Exclusions- Bipolar and Psychosis

If a potential recruit is excluded on the basis of a self-reporting at the screening questionnaire a previous diagnosis of Bipolar disorder or psychosis then would be automatically provided with the following information:

"**You have reported that you have previously received a diagnosis of either bipolar disorder or psychosis.**

Because this study is focused on treating anxiety and depression, rather than treating bipolar disorder or psychosis, the current study is not suitable for you at this time. The internet treatment has not been designed to help with these particular difficulties so we are sorry to say that taking part in the study would not be in your best interests at this time. Thank you for your interest.

Your GP or relevant medical professional is the best person to decide what help you need.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

Alongside your GP, there are other services available to you to provide information and support:

University specific support:

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- For students at the University of Oxford, there are a wide range of wellbeing and support services - https://www.ox.ac.uk/students/welfare
- For students at the University of Southampton, there are a wide range of wellbeing and support services – https://www.southampton.ac.uk/studentservices/support-wellbeing.page
- For students at Newcastle University, there are a wide range of wellbeing and support services – https://www.ncl.ac.uk/wellbeing/
- For students at King's College London, there are a wide range of wellbeing and support services - https://www.kcl.ac.uk/wellbeing

Useful **WEBSITES** that you can access directly below include:

- **YoungMinds** are there to make sure all young people get the best possible mental health support and have the resilience to overcome life's difficulties. They provide lots of resources to help with young person's mental health: https://youngminds.org.uk/find-help/
- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/
  - **For bipolar disorder:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/bipolar-disorder/about-bipolar-disorder/?o=1142#.XGQJJVX7SUk
  - **For psychosis:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/psychosis/#.XGQI_IX7SUk

  - **For schizophrenia**: https://www.mind.org.uk/information-support/types-of-mental-health-problems/schizophrenia/about-schizophrenia/?o=6266#.XGQJQIX7SUk
  - **For apps to help with your wellbeing and mental health:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
- **BipolarUK** National charity dedicated to supporting individuals with bipolar, their families and carers. Their websites has information leaflets and links to support, including a peer support line https://www.bipolaruk.org/
- **Rethink Mental Illness**. Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
  - **Toolkit for young people with questions or worries about their mental health:** https://www.rethink.org/media/1020652/ResourceFinal.pdf
- **There are a series of NHS self-help guides which can be found here** https://web.ntw.nhs.uk/selfhelp/
- **There are more guides and online courses here:** https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

Alternatively, here are **HELPLINES** you can ring to talk to someone about what how you are feeling

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org

- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org

7. **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
8. **Maytree** is a registered charity supporting people in suicidal crisis and is open for calls and emails 24 hours a day. **– 020 7263 7070,** maytree@maytree.org.uk

- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

If you find your symptoms particularly distressing or have thoughts about ending your life then please go to the nearest emergency room, or immediately contact your GP.

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**.

5) Exclusions- substance dependence

If a potential recruit is excluded on the basis of a self-reporting at the screening questionnaire a previous diagnosis of substance dependence then would be automatically provided with the following information:

"**You have reported that you have previously received a diagnosis of alcohol or substance disorder.**
Because this study is focused on treating anxiety and depression, rather than treating alcohol or substance disorder, the current study is not suitable for you at this time. The internet treatment has not been designed to help with these difficulties so we are sorry to say that taking part in the study would not be in your best interests at this time. Thank you for your interest.

Your GP or relevant medical professional is the best person to decide what help you need.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

Alongside your GP, there are other services available to you to provide information and support:

University specific support:

- For students at the University of Exeter, there are a wide range of wellbeing and support services - https://www.exeter.ac.uk/students/wellbeing/
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- For students at the University of Oxford, there are a wide range of wellbeing and support services - https://www.ox.ac.uk/students/welfare
- For students at the University of Southampton, there are a wide range of wellbeing and support services – https://www.southampton.ac.uk/studentservices/support-wellbeing.page
- For students at Newcastle University, there are a wide range of wellbeing and support services – https://www.ncl.ac.uk/wellbeing/
- For students at King's College London, there are a wide range of wellbeing and support services - https://www.kcl.ac.uk/wellbeing

Useful **WEBSITES** that you can access directly below include:

- **Alcoholics Anonymous:** They offer telephone, online and face-to-face help and advice related to alcohol or a drinking problem.
  https://www.alcoholics-anonymous.org.uk/

  FRANK: For friendly, confidential drugs advice, call FRANK on: **0300 123 6600**. Or you can access their website at:
  http://www.talktofrank.com

- **YoungMinds** are there to make sure all young people get the best possible mental health support and have the resilience to overcome life's difficulties. They provide lots of resources to help with young person's mental health: https://youngminds.org.uk/find-help/
- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/

    - **For apps to help with your wellbeing and mental health:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
- **Rethink Mental Illness**. Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
    - **Toolkit for young people with questions or worries about their mental health:** https://www.rethink.org/media/1020652/ResourceFinal.pdf
- **There are a series of NHS self-help guides which can be found here** https://web.ntw.nhs.uk/selfhelp/
- **There are more guides and online courses here:** https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

Alternatively, here are **HELPLINES** you can ring to talk to someone about what how you are feeling

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- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org

9. **SANE** offers support to anyone coping with mental illness, including concerned relatives or friends. The SANE helpline **0845 767 8000** is available 7 days a week from 6.pm-11 pm
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If you find your symptoms particularly distressing or have thoughts about ending your life then please go to the nearest emergency room, or immediately contact your GP.

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**.

6) Exclusions- receiving current therapy elsewhere

If potential participants are excluded on the basis of receiving current therapy elsewhere then they would be provided with the following screen:

"Your responses to these questions indicate you are currently receiving psychological therapy for your mental health.

Because this trial is focused on testing a psychological internet treatment for anxiety and depression, currently receiving another psychological therapy means that this study is not suitable for you at this time. However, once you complete your course of psychological therapy, you may be eligible for the study, and if you are still interested, we recommend returning to the trial website and completing the screening questions again to see if you can join the study. Thank you for your interest.

If you have concerns about your current therapy, your GP or therapist is the best person to talk to.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

If you do feel like you need some extra help as well as your GP and current therapy, there are many other services available to get you through this difficult time:

University specific support:

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Useful **WEBSITES** that you can access directly below include:

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    - **For info about depression:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/depression/#.XGQRn1X7SUk
    - **For apps to help with your mental health and wellbeing:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
    - **For info about mindfulness,** a technique you can learn which involves making a special effort to notice what's happening in the present moment. Many people find mindfulness helps them manage their day-to-day wellbeing. https://www.mind.org.uk/information-support/drugs-and-treatments/mindfulness/#.XGQBhFX7SUk
- **Rethink Mental Illness** Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
    - Toolkit for young people with questions or worries about their mental health: https://www.rethink.org/media/1020652/ResourceFinal.pdf
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If you find your symptoms particularly distressing or have thoughts about ending your life, go to the nearest emergency room, or **immediately contact your GP.**

7) Exclusions- receiving antidepressant medications

If potential participants are excluded on the basis of receiving current antidepressant medications then they would be provided with the following screen:

"Your responses to these questions indicate you are have recently started or changed medication for anxiety or depression.

Because this trial is focused on testing a psychological internet treatment for anxiety and depression, we need to be able to rule out other possible causes for any improvement such as taking medication for anxiety and depression. We therefore require participants to be on a stable dose of a medication for at least four weeks before entering the study, which means that this study is not suitable for you just now. However, once you have been on the same dose of your medication for at least four weeks, you can return and check your eligibility again. Thank you for your interest.

If you have concerns about your current medication, your GP is the best person to talk to.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

If you do feel like you need some extra help as well as your GP and current therapy, there are many other services available to get you through this difficult time:

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    - **For info about depression:** https://www.mind.org.uk/information-support/types-of-mental-health-problems/depression/#.XGQRn1X7SUk
    - **For apps to help with your mental health and wellbeing:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
    - **For info about mindfulness,** a technique you can learn which involves making a special effort to notice what's happening in the present moment. Many people find mindfulness helps them manage their day-to-day wellbeing. https://www.mind.org.uk/information-support/drugs-and-treatments/mindfulness/#.XGQBhFX7SUk
- **Rethink Mental Illness** Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
    - Toolkit for young people with questions or worries about their mental health: https://www.rethink.org/media/1020652/ResourceFinal.pdf
- **There are a series of NHS self-help guides which can be found here** https://web.ntw.nhs.uk/selfhelp/
- **There are more guides and online courses here:** https://www.cci.health.wa.gov.au/Resources/Looking-After-Yourself

Alternatively, here are **HELPLINES** you can ring to talk to someone about what how you are feeling

- **Papyrus 0800 068 4141 or text: 07786 209697** offers National support to young people up to age 35 who are feeling suicidal. (Monday-Friday 10:00am-5:00pm and 7:00pm-10:00pm; 2:00pm-5:00pm on weekends, pat@papyrus-uk.org

- The **Samaritans 08457 90 90 90** Freephone (UK and Republic of Ireland): 116 123 (24 hours),offer a confidential service so you can talk about your feelings, you can contact them at www.samaritans.org, Email: jo@samaritans.org

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- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

If you find your symptoms particularly distressing or have thoughts about ending your life, go to the nearest emergency room, or **immediately contact your GP.**

8) Exclusions- under the age of 16

If potential participants are excluded on the basis of being under the age of 16 then they would be provided with the following screen:

“This research requires that participants can provide their own informed consent – which in the UK requires you to be aged 16 or over. Because you indicated that you are aged under 16, you are therefore not eligible for the study. Thank you for your interest. We will be recruiting for over a year so if you are over 16 during the next year, you would be able to reapply for the study via our website.

If you have any concerns about your wellbeing or mental health, your GP is the best person to decide what help you need.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

Alongside your GP, there are other services available to you to provide information and support:

University specific support:

- For students at the University of Exeter, there are a wide range of wellbeing and support services - https://www.exeter.ac.uk/students/wellbeing/
- For students at the University of Cardiff, there are a wide range of wellbeing and support services - https://www.cardiff.ac.uk/study/student-life/student-support
- For students at the University of Oxford, there are a wide range of wellbeing and support services - https://www.ox.ac.uk/students/welfare
- For students at the University of Southampton, there are a wide range of wellbeing and support services – https://www.southampton.ac.uk/studentservices/support-wellbeing.page
- For students at Newcastle University, there are a wide range of wellbeing and support services – https://www.ncl.ac.uk/wellbeing/

  - For students at King's College London, there are a wide range of wellbeing and support services - https://www.kcl.ac.uk/wellbeing

Useful **WEBSITES** that you can access directly below include:

- **YoungMinds** are there to make sure all young people get the best possible mental health support and have the resilience to overcome life's difficulties. They provide lots of resources to help with young person's mental health: https://youngminds.org.uk/find-help/
- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/
- **For apps to help with your wellbeing and mental health:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
- **Rethink Mental Illness**. Provide expert advice and information to everyone affected by mental health problems, and provide services and groups; including resources specific to young people https://www.rethink.org/living-with-mental-illness/young-people
  - **Toolkit for young people with questions or worries about their mental health:** https://www.rethink.org/media/1020652/ResourceFinal.pdf
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- **Young Minds Crisis Messenger** provides free, 24/7 crisis support across the UK if you are experiencing a mental health crisis. If you need urgent help text YM to 85258. Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.
- **CALM 0800 58 58 58** (Daily 17:00-midnight) Offers support to young men in the UK who are down or in a crisis, www.thecalmzone.net
- **The Mix**, Freephone: 0808 808 4994 (13:00-23:00 daily), If you're under 25 you can talk to The Mix for free on the phone, by email or on their webchat. You can also use their phone counselling service, or get more information on support services you might need. www.themix.org.uk

If you find your symptoms particularly distressing or have thoughts about ending your life then please go to the nearest emergency room, or immediately contact your GP.

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**."

9) Exclusions- not a student at a UK university

If potential participants are excluded on the basis of not being a student at a UK university then they would be provided with the following screen:

"This research is focused on students (undergraduate and postgraduate) at UK universities. Because you do not indicate that you were at a UK university, you are not eligible for this research. Thank you for your interest.

If you have any concerns about your wellbeing or mental health, your GP is the best person to decide what help you need.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

Alongside your GP, there are other services available to you to provide information and support:

Useful **WEBSITES** that you can access directly below include:

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- **Mind** The Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem. They provide information about mental health problems and potential treatments as well as tips for everyday living. https://www.mind.org.uk/
- **For apps to help with your wellbeing and mental health:** https://www.mindcharity.co.uk/advice-information/how-to-look-after-your-mental-health/apps-for-wellbeing-and-mental-health/
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If you find your symptoms particularly distressing or have thoughts about ending your life then please go to the nearest emergency room, or immediately contact your GP.

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**."

10) Message for participants who are eligible for feasibility trial but not from Exeter university:

"Thank you for completing the NURTURE U trial screener. Based on your answers to the screening questions, it appears that you are currently not particularly stressed, worried, anxious or feeling down – this means that you are currently not eligible for any of our trials at this time because they are focused on helping people experiencing elevated symptoms or stress. We wish you all the best and hope that you continue to feel well.

Have a nice day!"

11) Message for participants who are eligible for Feasibility/Acute/Rumination but do not consent after completing screening:

"Thank you for completing the Nurture-U trials screener and for reading our information sheet and consent form. You are only able to proceed further into the study if you consent to participate in the study. Because you have not consented to join the study, you are unable to proceed further. If this is a mistake and you do want to take part, please go back and complete the consent form. Thank you for your interest.

If you have any concerns about your wellbeing or mental health, your GP is the best person to decide what help you need.

You can contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year.

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- For students at Newcastle University, there are a wide range of wellbeing and support services – https://www.ncl.ac.uk/wellbeing/
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If you find your symptoms particularly distressing or have thoughts about ending your life then please go to the nearest emergency room, or immediately contact your GP.

Talking to people who understand can make it much easier to manage your symptoms so **please do call your GP or one of the specialist helplines above**."

12) Introduction/welcome information for the Nurture-U trials screening page:

"Thank you for your interest in taking part in one of the Nurture-U research trials to improve university student mental health.

The Nurture-U project includes several studies to investigate different interventions to help university students including a study of a mobile app to increase confidence and reduce worry, and a study comparing therapist-supported versus self-directed digital cognitive-behavioural therapy for anxiety and depression, to find out what works best for whom. We have a brief online survey before you can proceed to these studies to assess if you are eligible and to then either direct you to the relevant study or to information about why the study is not suitable for you.

We ask you to complete brief online questions about demographics, symptoms and coping styles. These questions should take less than 5 minutes to complete."

Risk Assessment and Reporting: telephone and email contact

All researchers and clinicians that have direct contact (by telephone or email) with recruits or participants will be familiar and trained how to use this SOP and will sign the delegation log to say that this has been done. The purpose of the SOP is to script the contact between researcher and participant so that the risk is assessed.

PIs/supervisors/clinicians (e.g., local psychiatrists or clinical psychologists) will also familiarise themselves with this SOP and provide researchers with their contact details in case the researcher needs advice. When clinical academic staff are away on leave, they should ensure appropriate cover is arranged to support researcher with advice on for any risk issues that might arise in their absence. The clinician is available to support and guide the researcher in responding to risk and where requested in communicating and providing guidance to the participant.

1) Telephone contact

When conducting telephone interviews in which risk may be disclosed, the interviewer should establish the telephone number and location of the participant at the start of the call, and clarify the boundaries of confidentiality:

'Hi, is that (name) this X from the Nurture-U trial, is now a convenient time to talk?' [or in response to answering a call direct from a participant – at which point we would ask for name and email, so we can identify them]

If yes 'This call is confidential and the only reason I would break that is if I thought you were at risk to yourself or others and it was in your best interests.

We just wanted to give you a call after your message to us in the email you sent / I would like to clarify what you are telling me now on the phone.

Can I just check where you are at the moment? [obtain details of location/address]

"I see that you've said / you mentioned that…….. (examples: if thoughts of death /"what is the point?" / "it might be better if I did not wake up",

"Has this gone as far as thinking about harming yourself or taking your own life?" If yes, or if already stated:

'These are common thoughts and can vary a lot in their severity and it's important to make sure you are receiving the right kind of support. So I would now like to ask you some more questions that will explore these feelings in a little more depth."

INTENTION

Have you had any intention to hurt yourself or take your own life? YES OR NO

PLANS

1 Do you know how you would take your own life? Yes / No

If **yes – ask for and record** details

2 Have you made any actual plans to end your life? Yes / No

If **yes – ask for and record** details

ACTIONS

3. Have you made any actual preparations to take your own life? Yes / No

If **yes – ask for and record** details

4. Have you ever attempted suicide in the past? Yes / No

If **yes – ask for and record** details

1. **PREVENTION**Is there anything stopping you taking your own life or harming yourself at the moment? Yes / No

If **yes – ask for and record** details

2. Do you feel that there is any immediate danger that you will harm yourself or take your own life? Yes / No

Ask for and record Details:

If yes to any of questions 1-4

- [if yes to 4 only, or yes to 1 only] I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? *(if they say yes)* I would advise you to make an appointment to see your GP to talk about these feelings.
- [if any of 1-3] Would you like us to write a letter to your GP letting them know how you are feeling? If yes, please can you give us your permission to do so *(and provide their contact details)*
- [all] I can also email you a list of website and helplines for people that have expertise at helping in just this kind of situation, would that be helpful?

If yes to 2 and 3 or to 6, request clinical input if not a clinician and say the following

- I am very concerned about your safety at this moment….

- I am not a clinician but I would like you to talk to one right now. With your permission I am going to call the site clinician/your GP to let them know how you are feeling and to arrange for you to receive immediate help/a call back. Can you provide their contact details?

In addition, If yes to question 6 [immediate risk]

- I think its best that you get emergency support at this time. I am going to call your GP/the emergency services and send them to your location.

Keep the participant on the phone while you call the clinician from another number or email.

If immediate risk is disclosed the interviewer should not hang up if at all possible.
In case contact is lost, the participant should be informed that the interviewer / supervisor will call them back straight away but that if they are unable to make contact the participant's G.P. or the emergency services will be informed. Good practice is to call /use a phone line for participants that (a) is mobile so

that researcher can contact clinical supervisor if physically proximal (b) have a second line to contact clinical supervisor (e.g., by text, teams) whilst maintaining conversation with participant.

2) E-mail contact

In the eventuality that participants send emails to researchers that indicate potential elevated suicide risk (e.g., talking about death, ending it all, seeing no hope, referring to suicide or self-harm, seeing no way out), then further follow-up steps will be taken, including attempts to respond to the participant to clarify the severity of the risk. These emails will provide guidance and signposting information (replicating the information provided on the automated webpage in response to reporting suicidality on the screening/assessment website) and enquire about risk following the questions above (e.g., asking about suicidal ideation, plans, preparation, prevention, means).

An email will be sent to the participant, acknowledging their potential distress and thoughts of death and self-harm, including the following questions:

Self Risk Q1 Are you currently experiencing any thoughts about suicide?

Self Risk Q2 Do you have any intention to hurt yourself or end your own life?

Self Risk Q3 Have you made any current plans to end your life or harm yourself?

Self Risk Q4 Do you have the means to harm yourself or end your life?

A template email for initial response is as follows, to be adapted to directly respond to details and concerns raised in specific email from the participant:

“Dear ,

Thank you for contacting us.

Your email suggested that you might have been having thoughts about harming or killing yourself. These thoughts can vary a lot from person to person. These may have just been brief passing thoughts or reflect a sense of feeling trapped, but without any intention to do anything. These thoughts are relatively common and not that unusual in people who feel stressed.
On the other hand, you may have been thinking about your death a lot, or you may have thought about ending your own life. You may have even have thought about how you might kill yourself or made a plan to end your life. In any of these cases, we strongly urge you to talk to someone about these thoughts, and in particular your GP or family doctor.

It would be useful to know more about the sort of thoughts you are having at the moment.
Are they just thoughts about death? Or are you having thoughts about ending your life or harming yourself?
If it is the latter, have you made any actual plans to end your life? Have you made any actual preparations to kill yourself? Is there anything stopping you killing or harming yourself at the moment?
I would appreciate you letting me know the answers to these questions, so I can help you as best I can.

If you are having thoughts of ending your life or harming yourself, I **advise you to contact your general practitioner or family doctor or mental health professional as soon as possible** and tell them how you are feeling. If you don't think you can stay safe, please go to the nearest hospital accident and emergency room or contact one of the suicide hotlines at Befrienders.org or Samaritans.org. If none of these options are available, please contact a family member, a trusted friend, or any other trusted person so that you won't be alone right now.

Throughout the UK, please contact your GP using the normal telephone number for your GP practice. If the surgery is not open, you will either be re-directed automatically to the out-of-hours GP service or you will be given another number to call. You can also **phone 111 to access the NHS 111 service**, which provides access to local NHS healthcare services in England, and is available 24 hours a day, 365 days a year. Details for out of hours services and support across the UK can be found in the leaflet on national out-of-hours services which has been attached to this email.

If you don't think you can stay safe, please go to the nearest hospital accident and emergency room. If none of these options are available, please contact a family member or a trusted friend, so that you won't be alone right now. If you have already made a plan, as best you can, please try and get rid of the means to harm yourself, whilst keeping yourself safe. It can also be helpful to focus on anything that may stop you from killing or harming yourself at the moment, such as thinking about your faith, loved ones, family and pets. It is important to remember that these feelings and urges do pass, and when individuals feel better, they are glad that they did not act on them. There are effective treatments that can help, and there is no need to struggle alone. Getting help may make it easier to manage your symptoms and to live the kind of life you would like to live.

Best wishes,
Researcher Name”

Similar actions will be taken for email responses as for telephone contacts (see section above). Follow-up emails may be necessary to either further clarify responses to questions, provide further guidance and support, or provide more detailed signposting for help.

Risk Assessment and Reporting: Risk register

All risk alerts whether via email or telephone contact will be logged on a risk register with any action taken, by whom and when (see below). Site researchers will follow up on risk alerts within 1 working day using the risk assessment and reporting SOP including responding to participants and registering the action taken. This will need to be logged at each local site and shared centrally with the lead site (Exeter) in an anonymised format.

Action to take after responding to immediate risk:

i. Document action taken on the risk log and a risk report form (see below).

ii. Telephone or send letter to GP documenting information gathered and action taken.

iii. Seek / offer supervision around support and debriefing as appropriate.

iv. Determine if AE/SAE reporting is necessary (Section 9).

GP letters have been provided to participating sites as part of the document packs reviewed by REC and the SAE reporting form can be found on the EDC and/or in the paper CRF pack.

Risk Report Form

Participant Trial Number

Suicide risk information: [note answers to all questions above re yes/no answers and details] *Intention:* *Plans:* *Actions:* *Prevention:* *Prior attempts:* *Immediate risk:* *Date reported: ___/___/___*
Additional notes / actions taken: *Date action taken: ___/___/___*

Researcher / assessor: _____ Signed: _____ Date: ___/___/___

Supervisor: _____ Signed: _____ Date: ___/___/___

Appendix B: Trial Measures

Baseline measures [pre-randomisation] – in order of administration first to last: G, G2, G3, G4, WEMWBS, H, I (WSAS) J, K, O, P, Q, R, S, T, U, V, W, X, Y, Z (including open questions at bottom of table)

Measure	Rationale	Further information
PHQ-9 (see appendix D)	Primary outcome – piped through from the screener	Standardised measure; as programmed for resilience and prevention trials
GAD-7 (see appendix E)	Primary outcome– piped through from screener	Standardised measure; as programmed for resilience and prevention trials
WEMWBS (7-item) (see appendix F)	Secondary outcome – mental wellbeing	Standardised measure; as programmed for resilience and prevention trials
WSAS (see appendix I)	Secondary outcome - functioning	as programmed for resilience and prevention trials
Gender (M/F/neither/both); sexual orientation, race/ethnicity, birthplace, educational attainment, topic of study, parent SES, physical health (see G in appendix)	Set of predictor variables for determining moderators and Individualised Treatment Rules*	Demographics (see appendix G); as programmed for resilience and prevention trials, **plus some additional questions as outlined in G2**
Past history of depression (see eQ10 in G; CIDI-SC in Q); perceived physical/mental health (see P); role impairment (WSAS above); mental /physical health symptoms (PHQ9, GAD7 above); cognitive functioning (see W), anger/irritability (see CIDI-SC in Q; **mental health history (see Q10 in G)**	Set of predictor variables for determining moderators and Individualised Treatment Rules*	Mental health history; **NEW QUESTIONS**
Sleep problems (see T); substance use (see S); generalized anxiety, panic, obsessive-compulsive disorder, posttraumatic stress disorder (see CIDI-SC in Q),	Set of predictor variables for determining moderators and Individualised Treatment Rules*	Co-morbid symptoms; **NEW QUESTIONS**

suicidal ideation, suicide attempt (see R)		
Current medications, healthcare utilization, lifetime mental health treatment (- see G2) current mental health treatment, orientations towards digital technology and interventions (See Z); **goals for intervention (see M), user preferences; perceived efficacy of intervention (see Z)**	Set of predictor variables for determining moderators and Individualised Treatment Rules*	Treatment engagement and related; **NEW QUESTIONS – including in demographic section re treatments received**
Family history of mental/emotional problems (see G); **adverse childhood experiences; childhood trauma (See G3, G4); high current stress severity, recent stressful life events**, **stress reactivity (See H)**;	Set of predictor variables for determining moderators and Individualised Treatment Rules*	Stress and Adversity; for current stress includes stress measures in appendix H; as programmed for resilience and prevention trials, PLUS **NEW QUESTIONS**
Brooding subscale of Ruminative Response scale (5-item); brief PSWQ	Set of predictor variables for determining moderators and Individualised Treatment Rules* - both piped through from screener	Coping styles, see appendix A and B; as programmed for resilience and prevention trials
Agreeableness; alexithymia; conscientiousness; emotionality; extraversion; hopelessness, openness, impulsivity, , attachment style, self-esteem, perceived control, problem-solving ability, mastery, resilience (see V, Y, J)	Set of predictor variables for determining moderators and Individualised Treatment Rules*	Personality; **NEW QUESTIONS** Resilience includes brief resilience scale (appendix J) (already programmed)
relationship quality (See U); loneliness (see U);	Set of predictor variables for determining moderators and Individualised Treatment Rules*	Social support; **NEW QUESTIONS**

Problem description – see in next column – To go in Z	Participant asked in open text box to "Describe a current problem that you are facing – please use at least 3 sentences to describe the nature of the difficult""	Responses can be rated for: Positivity-negativity; self-focus; abstract vs concreteness; **NEW QUESTIONS**
Therapy expectation (see in next column) -to go in Z	Participant asked to describe in open text box what they expect from therapy: "What do you expect from participating in this study and using this online therapy?"	**NEW QUESTIONS**
Problem-solving skills	2 items to solve from the Means Ends Problem Solving Task	**NEW QUESTIONS**

Outcome measures (*identical to the outcome measures for the prevention trial, except that only administered at 3 months plus the addition of two measures related to therapy use and experience, and no LIDAS measure*). In order of administration

Measure	Rationale	Further information
PHQ-9 (see D in appendix below)	Primary outcome	As in Prevention trial
GAD-7 (see E in appendix below)	Primary outcome	As in Prevention trial
WEMWBS (see F in appendix below, 7-item)	Secondary outcome – mental wellbeing	As in Prevention trial
Measures of stress (see H in appendix below)	Secondary outcome, potential moderator of effect	As in Prevention trial
WSAS (see I in appendix below)	Secondary outcome – social and work functioning	As in Prevention trial
5-item Brooding scale (see A in appendix below)	Secondary outcome	Test whether intervention reduces worry and rumination As in Prevention trial

Short-form Penn State Worry Questionnaires (see B in appendix below)	Secondary outcome	Test whether intervention reduces worry and rumination As in Prevention trial
Brief Resilience Scale (see J in appendix below)	Secondary outcome	As in Prevention trial
Academic grades self-report (see K in Appendix below)	Secondary outcome to assess impact on academic studies	As in Prevention trial
Use of services /treatment received–incorporating NHS and student services (see O in appendix below)	To understand level of treatment sought and received – from list of student, NHS, and other options	As in Prevention trial
Use and application of intervention	"How many days in the past 3 months did you log on and use the internet therapy"? Response options 0-90 "How many days in the past month did you use any of the skills you learned in the internet therapy?" Response option 0-30 "On average about how many times per day do you use these skills?" (0+) "In the past month, how helpful were the skills you learnt in the internet treatment?" Response options – very helpful; somewhat; a little; not at all helpful; they made things worse	NEW TO ACUTE TRIAL AS BOTH ARMS INVOLVE TREATMENT
Satisfaction with intervention	Adapted Client Satisfaction Questionnaire – Internet-based interventions (Bos et al., JMIR 2016) Scored 1= "Does not apply to me" to 4="Does totally apply to me. Replaced "service" with "training" – may adapt to "therapy" 1. The online therapy was of high quality 2. I received the kind of therapy I wanted	

	3. The therapy has met my needs 4. I would recommend this therapy to a friend, if she or he were need of similar help 5. I am satisfied with the amount of help I received 6. The therapy helped me deal with my problems more effectively 7. In an overall general sense I am satisfied with the therapy 8. I would come back to this therapy if I were to seek help again Plus How much did this treatment help with the specific problem that led you to therapy? Made things a lot better 1, made things somewhat better 2, made no difference 3, made things somewhat worse 4, made things a lot worse 5	
Open text questions about therapy	1. What did you find most helpful about this therapy? 2. What did you find difficult or unhelpful about the therapy? 3. How could the therapy be improved? How you have any problems with the internet treatment? Has any aspect made you feel worse?	Questions to assess response to treatment and possible harms

Mediator measures – repeated weekly for 8 weeks post-randomisation, taking less than 5 minutes to complete, 23 items to rate [*identical to those to be programmed for the prevention trial]*

Measure	Rationale	Further information
PHQ-2 (see L in appendix below	Brief measure of depression	2-item scale
GAD-2 (see L in appendix below)	Brief measure of anxiety	2-item scale
Stress **How much stress have you had in your life over the past 7 days?** (StressSev). Scored as: Very severe (4), severe (3), moderate (2), mild (1), none (0), list with circle to select	Single item to assess stress	laid out with ratings as choice buttons along horizontal paralleling other questions in this section
During the past 7 days in a stressful or upsetting situation: a) How often did you take a moment to question your interpretation of what was happening when you got upset (e.g., look for a more positive or balanced explanation; weigh up different accounts, try and put things in perspective)? 0= Never, 1=Rarely, 2=Occasionally, 3=Sometimes, 4=Often, 5= Very often, 6= Always; (b) How helpful was this in making you feel better? 0=Not at all helpful, 1 = Slightly helpful, 2=Somewhat helpful, 3=Moderately helpful, 4= Fairly helpful, 5=Very helpful, 6=Extremely helpful, N/A=Didn't do this last week During the past 7 days in a stressful or upsetting situation: (a) How often did you plan and/or do activities you knew you would enjoy?	Use of cognitive and behavioural skills, 6-items, these reflect different potential strategies that individuals may use and that may be provided within the intervention	Brief questions to capture cognitive and behavioural strategies from Cognitive and Behavioral Response to Stress Scale (CB-RSS) Miner et al., 2015, with addition based on student feedback, see Appendix M for example of questionnaire

0= Never, 1=Rarely, 2=Occasionally, 3=Sometimes, 4=Often, 5= Very often, 6= Always; (b) How helpful was this in making you feel better? 0=Not at all helpful, 1 = Slightly helpful, 2=Somewhat helpful, 3=Moderately helpful, 4= Fairly helpful, 5=Very helpful, 6=Extremely helpful, N/A=Didn't do this last week During the past 7 days in a stressful or upsetting situation: (a) How often did you use relaxation or similar techniques to soothe, focus or calm yourself (e.g., meditation, breathing, focusing attention, imagery)? 0= Never, 1=Rarely, 2=Occasionally, 3=Sometimes, 4=Often, 5= Very often, 6= Always; (b) How helpful was this in making you feel better? 0=Not at all helpful, 1 = Slightly helpful, 2=Somewhat helpful, 3=Moderately helpful, 4= Fairly helpful, 5=Very helpful, 6=Extremely helpful, N/A=Didn't do this last week		
During the past 7 days worry is something that "I do automatically" "I do without thinking" "I start doing before I realise I'm doing it" Each of 3 items rated on 1 to 7 scale from Strongly disagree to Strongly agree [Strongly disagree, Moderately Disagree, Slightly Disagree, Neither Agree or Disagree, Slightly Agree, Moderately Agree, Strongly Agree)	Change in habit applied to worry, 3 items – to assess whether rumination/worry becomes more or less of a habit; the intervention focuses on changing habit	Adapted items from SRHI index, Gardner et al., 2012, laid out with ratings as choice buttons along horizontal paralleling other questions in this section
During the past 7 days problem solving is something that "I do automatically" "I do without thinking" "I start doing before I realise I'm doing it"	Change in habit applied to problem-solving, 3 items – to assess whether more helpful responsive becomes more or less of a habit	Adapted items from SRHI index, Gardner et al., 2012, laid out with ratings as choice buttons along horizontal paralleling other questions in this section

Each of 3 items rated on 1 to 7 scale from Strongly disagree to Strongly agree (Strongly disagree, Moderately Disagree, Slightly Disagree, Neither Agree or Disagree, Slightly Agree, Moderately Agree, Strongly Agree)		
Please indicate how often you behaved in the stated manner during the past 7 days on a scale from 1 (Almost never) to 5 (Almost always). "When I'm going through a very hard time, I give myself the caring and tenderness I need"; "When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people"	Self-compassion, 2-items; the intervention includes a self-compassion element	Selected items from SCS-SF (Self-Compassion Scale – Short Form), items from Self-kindness and Common humanity scales – see N in appendix for example of shortened questionnaire
2-items from Brooding questionnaire – "Indicate whether you never, sometimes, often or always thought or did each of the following when you felt sad, down or depressed over the past 7 days. A. Think "Why do I always react this way?" B. Think "Why can't I handle things better?"	Rumination, 2-items	Adapted from the RRS-B-Brooding 5-item questionnaire, Treynor et al., 2003, see Appendix A for the full questionnaire – this uses two items from it
"In the last seven days I feel better prepared to handle situations I could not handle before" rated using a seven-point Likert scale ranging from −3 ("absolutely not true), 0 ("neither nor") and +3 ("absolutely true").	Self-efficacy/Mastery	Laid out as horizontal rating scale underneath the description item
"In the last seven days, I understand myself and my problems better" rated using a seven-point Likert scale ranging from −3 ("absolutely not true), 0 ("neither nor") and +3 ("absolutely true").	Problem clarification	Laid out as horizontal rating scale underneath the description item

APPENDIX C: DETAILED APPENDIX OF MEASURES

A. 5-item Brooding subscale of Ruminative Response Scale (screen/outcome)

People think and do many different things when they feel sad, blue or depressed. Please read each of the items below and indicate whether you almost never, sometimes, often or almost always think or do each one when you feel sad, down or depressed. Please indicate what you generally do, not what you think you should do.

		Almost Never	Sometimes	Often	Almost Always
1.	Think “What am I doing to deserve this?”	1	2	3	4
2.	Think “Why do I always react this way?”	1	2	3	4
3.	Think about a recent situation, wishing it had gone better	1	2	3	4
4.	Think “Why do I have problems other people don’t have?”	1	2	3	4
5.	Think “Why can’t I handle things better?”	1	2	3	4

B. Short form Penn State Worry Questionnaire

PSWQ -S – 8 item measure of tendency towards worry. Used as outcome, assessment of risk (high vs low) and personalisation. EC-Regulation measure.High risk= PSWQ-A: upper quartile (75%, >=26)

Select the answer that best describes how typical or characteristic each item is of you.

		not at all typical		somewhat typical		very typical
		1	2	3	4	5
1.	My worries overwhelm me.	❑	❑	❑	❑	❑
2.	Many situations make me worry.	❑	❑	❑	❑	❑
3.	I know I should not worry about things but I just cannot help it.	❑	❑	❑	❑	❑
4.	When I am under pressure I worry a lot.	❑	❑	❑	❑	❑
5.	I am always worrying about something.	❑	❑	❑	❑	❑
6.	As soon as I finish one task, I start to worry about everything else I have to do.	❑	❑	❑	❑	❑
7.	I have been a worrier all my life.	❑	❑	❑	❑	❑
8.	I notice that I have been worrying about things.	❑	❑	❑	❑	❑

Scored – all items in positive direction, higher score more worry, scored from range of 8-40

C. Adapted LIDAS to determine if current major depressive episode or history of depression including screening for history of other disorders

For Screener/baseline:

START SCORE 0 ON current MDE_KEY CRITERIA variable, 0 ON TOTAL SYMPTOMS_CURRENT MDE variable; START SCORE 0 ON past MDE_KEY CRITERIA variable, 0 ON TOTAL SYMPTOMS_PAST MDE variable;

1. Have you ever in your life had a period of at least two weeks when you felt sad, empty, or depressed?

□1 Yes GO TO 1A

□0 No ► go to question 3

-page break-

1A. In the last month, have you had a period of at least two weeks when you felt sad, empty, or depressed?

□1 Yes GO TO 2

□0 No ► go to question 2A

-page break-

2. For the next question, think about the period of two weeks in the past month when these feelings were at their worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 5 SCORE +1 ON CURRENT MDE KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS CURRENT MDE

□0 Less often Go to 2A

-page break-

2A. For the next question, think about the period of two weeks in your life when these feelings were at their worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 5C SCORE +1 ON PAST MDE KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS PAST MDE

□0 Less often Go to 3

-page break-

3. Have you ever had a period of at least two weeks during which you lost interest in most things like hobbies, work, or activities that usually give you pleasure?

□1 Yes GO TO 3A

□0 No ► go to 46 END –,

-page break-

3A. In the past month, have you had a period of at least two weeks during which you lost interest in most things like hobbies, work, or activities that usually give you pleasure?

□1 Yes GO TO 4

□0 No ► go to 4A –,

-page break-

4. For the next question, think about the period of two weeks in the past month when your loss of interest was at its worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 7 SCORE +1 ON CURRENT MDE-KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS CURRENT MDE

□0 Less often ► go to 4A

-page break-

4A. For the next question, think about the period of two weeks in your life when your loss of interest was at its worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 25 SCORE +1 ON PAST MDE- KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS PAST MDE

□0 Less often ► go to 46 END

-page break-

5. During this period in the past month in which you felt sad, empty, or depressed, did you have a period of at least two weeks when you lost interest in most things like hobbies, work, or activities that usually give you pleasure?

□1 Yes GO TO 6

□0 No ► go to question 5A

-page break-

5A. Have you ever had a period of at least two weeks during which you lost interest in most things like hobbies, work, or activities that usually give you pleasure?

□1 Yes GO TO 5B

□0 No ► go to 7 –,

-page break-

5B. For the next question, think about the period of two weeks in your life when your loss of interest was at its worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 7 SCORE +1 ON PAST MDE- KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS PAST MDE

□0 Less often ► go to 7

-page break-

5C. During this period in which you felt sad, empty, or depressed, did you have a period of at least two weeks when you lost interest in most things like hobbies, work, or activities that usually give you pleasure?

□1 Yes GO TO 6C

□0 No ► go to question 6D

-page break-

6. For the next question, think about the period of two weeks in the past month when your loss of interest was at its worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day SCORE +1 ON CURRENT MDE - KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS-CURRENT MDE go to Question 7

□0 Less often go to question 6B

-page break-

6B. For the next question, think about the period of two weeks in your life when your loss of interest was at its worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 7 SCORE +1 ON PAST MDE- KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS PAST MDE

□0 Less often ► go to 7

-page break-

6C. For the next question, think about the period of two weeks in your life when your loss of interest was at its worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 6D SCORE +1 ON PAST MDE- KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS PAST MDE

□0 Less often ► go to 6D

-page break-

6.D. During the past month did you have a period of at least two weeks when you lost interest in most things like hobbies, work, or activities that usually give you pleasure?

□1 Yes GO TO 6E

□0 No ► go to question 25

-page break-

6E. For the next question, think about the period of two weeks in the past month when your loss of interest was at its worst. During this period of two weeks, how often did you feel this way?

□1 Almost every day, most of the day ► go to question 7 SCORE +1 ON CURRENT MDE-KEY CRITERIA CODE; SCORE+ 1 ON TOTAL SYMPTOMS CURRENT MDE

□0 Less often ► go TO 25

-page break-

7. People who have periods in which they feel sad, empty, or depressed or experience a loss of interest, often have other problems at the same time. In the past month, during this period of at least two weeks when you felt sad, empty, or depressed or lose interest in things:

7. … did you lack energy or feel tired more than usual?

□1 Yes SCORE +1 ON TOTAL SYMPTOMS-CURRENT MDE, GO TO 8

□0 No GO TO 8

8. … have less appetite than usual, almost every day?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE. GO TO 9

□0NO GO TO 9

9. …did you lose weight without trying to, as much as a kilo a week during several weeks?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE UNLESS SCORED ON 8, GO TO 10

□0 No ► go to question 11

-page break-

10. About how much weight did you lose in these weeks? □□ kg go to question 14

-page break-

During this period of at least two weeks when you felt sad, empty or depressed or experienced a loss of interest in things:

11. … did you have a much larger appetite than usual, and this almost every day for at least two weeks?

□2 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE, GO TO 12

□1 Yes, only because of pregnancy or a growth spurt GO TO 12

□0 No GO TO 12

12. … did your appetite increase so much that you gained weight, as much as a kilo a week during several weeks?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE UNLESS SCORED ON 11, GO TO 13

□0 No ► go to question 14

-page break-

13. About how much weight did you gain in these weeks? □□ kg

During this period of at least two weeks when you felt sad, empty, or depressed or experienced a loss of interest in things:

14. …. Did you have trouble sleeping almost every night, either trouble falling asleep, waking in the middle of the night, or waking up too early?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE GO TO 15

□0 No ► go to question 15

15. …. Did you wake up at least two hours before you wanted to, every day for at least two weeks?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE UNLESS SCORED ON 14

□0 No

16. …. Were you sleeping too much almost every day?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE

□0 No

-page break-

During this period of at least two weeks when you felt sad, empty or depressed or experienced a loss of interest in things:

17. …. Did you talk or move more slowly than is normal for you almost every day, and did other people noticed this?

□2 Yes, I talked or moved more slowly and other people noticed SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE

□1 Yes, I talked or moved more slowly but other people did not notice

□0 No

18. …. did you have to be moving all the time, that is, you couldn't sit still and paced up and down or couldn't keep your hands still when sitting, and did other people noticed this?

□2 Yes, I had to be moving all the time and other people noticed SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE UNLESS SCORED ON 17

□1 Yes, I had to be moving all the time but other people did not notice

□0 No

-page break-

19. During this period of two weeks, did you have a lot more trouble concentrating than usual?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE

□0 No

20. During this period, were you unable to make up your mind about things you ordinarily had no trouble deciding about?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE UNLESS SCORED ON 19

□0 No

21. People sometimes feel down on themselves, no good, or worthless. During this period of two weeks, did you feel guilty or worthless?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE

□0 No

22. During this period of two weeks, did you think a lot about death – either your own, someone else's, or death in general?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-CURRENT MDE

□0 No

-page break-

For the next question, please think about the period in the past month of <u>at least two weeks</u> when you felt sad, empty, or depressed or experienced a loss of interest in things.

23. During this period of at least two weeks did it seriously interfere with your ability to do your job, or take care of your house, family, or yourself?

□1 Yes

□0 No

24. About how long has this period of experiencing these symptoms lasted? You may give an estimate.

_____ Weeks

MEETS CRITERIA FOR CURRENT MDD IF CURRENT-MDE-KEY CRITERIA >=1 AND TOTAL SYMPTOMS-CURRENT MDE >=5

IF MEETS CRITERIA FOR CURRENT MDE, THEN GO TO 42; IF NOT MEET CRITERIA FOR CURRENT MDE, go to 25.

25. People who have periods in which they feel sad, empty, or depressed or experience a loss of interest, often have other problems at the same time. During this period of at least two weeks when you felt sad, empty, or depressed or lose interest in things:

25. … did you lack energy or feel tired more than usual?

□1 Yes SCORE +1 ON TOTAL SYMPTOMS-PAST MDE, GO TO 26

□0 No GO TO 26

26. … have less appetite than usual, almost every day?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE. GO TO 27

□0NO GO TO 27

27. …did you lose weight without trying to, as much as a kilo a week during several weeks?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE UNLESS SCORED ON 26, GO TO 28

□0 No ► go to question 29

-page break-

28. About how much weight did you lose in these weeks? □□ kg go to question 32

-page break-

During this period of at least two weeks when you felt sad, empty or depressed or experienced a loss of interest in things:

29. … did you have a much larger appetite than usual, and this almost every day for at least two weeks?

□2 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE, GO TO 30

□1 Yes, only because of pregnancy or a growth spurt GO TO 30

□0 No GO TO 30

30. … did your appetite increase so much that you gained weight, as much as a kilo a week during several weeks?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE UNLESS SCORED ON 29, GO TO 31

□0 No ► go to question 32

-page break-

31. About how much weight did you gain in these weeks? □□ kg

During this period of at least two weeks when you felt sad, empty, or depressed or experienced a loss of interest in things:

32. …. Did you have trouble sleeping almost every night, either trouble falling asleep, waking in the middle of the night, or waking up too early?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE GO TO 33

□0 No ► go to question 33

33. …. Did you wake up at least two hours before you wanted to, every day for at least two weeks?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE UNLESS SCORED ON 32

□0 No

34. …. Were you sleeping too much almost every day?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE go to 35

□0 No go to 35

-page break-

During this period of at least two weeks when you felt sad, empty, or depressed or experienced a loss of interest in things:

35. …. Did you talk or move more slowly than is normal for you almost every day, and did other people noticed this?

□2 Yes, I talked or moved more slowly and other people noticed SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE go to 36

□1 Yes, I talked or moved more slowly but other people did not notice go to 36

□0 No go to 36

36. …. did you have to be moving all the time, that is, you couldn't sit still and paced up and down or couldn't keep your hands still when sitting, and did other people noticed this?

□2 Yes, I had to be moving all the time and other people noticed SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE UNLESS SCORED ON 35

□1 Yes, I had to be moving all the time but other people did not notice

□0 No

-page break-

37. During this period of two weeks, did you have a lot more trouble concentrating than usual?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE

□0 No

38. During this period, were you unable to make up your mind about things you ordinarily had no trouble deciding about?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE UNLESS SCORED ON 37

□0 No

39. People sometimes feel down on themselves, no good, or worthless. During this period of two weeks, did you feel guilty or worthless?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE

□0 No

40. During this period of two weeks, did you think a lot about death – either your own, someone else's, or death in general?

□1 Yes SCORE + 1 ON TOTAL SYMPTOMS-PAST MDE

□0 No

-page break-

For the next question, please think about the period of at least two weeks when you felt sad, empty, or depressed or experienced a loss of interest in things.

41. During this period of at least two weeks did it seriously interfere with your ability to do your job, or take care of your house, family, or yourself?

□1 Yes

□0 No

42. About how long did the longest of periods like this last? *You may give an estimate.*

□□□ Weeks

43. How many periods like this have you had in your life in total?

□1 1 (just this one) □2 2 □3 3 □4. 4 □5 5 or more

44. Did you have a period like this in the last 3 months?

□1 Yes □0 No

45. About how old were you the first time you had a period like this? (whether or not you received any help for it)

□□ Years old

Section to check on past history of mental health and other exclusion criteria

46. Have you ever been diagnosed with a mental health disorder or been treated for a mental health disorder by a professional or medical doctor? YES or NO

IF NO, skip to end

-page break-

If YES:

47. Please select the disorders that you have been diagnosed with and/or received treatment by a professional or medical doctor ever in your life. You can select more than one answer.

select from the drop-down menu:

□a An eating disorder

□b ADD/ADHD

□c An anxiety disorder

□d Panic disorder

□e Phobia

□f Post traumatic stress disorder

□g Obsessive compulsive disorder

□h Bipolar disorder (manic depression) links to Bipolar/Psychosis feedback exclusion page

□i Schizophrenia or psychosis links to Bipolar/Psychosis feedback exclusion page

□J Alcohol or substance use disorder – link to substance use feedback exclusion page

□K Current treatment for Anxiety or Depression

If yes to K– goes to question asking – Are you currently receiving psychological treatment for anxiety or depression from a health professional (e.g., cognitive-behavioural therapy, counselling)? Yes or No

If yes, How many sessions received? Number response option

If yes, How many further sessions planned? Number response option

If yes, and sessions received < 20 and sessions planned > = 4 excluded for current treatment but given message can return to trial once treatment completed.

If yes to K, “Are you currently taking any medication for anxiety and/or depression?” If yes, what medication and dose in open text box.

How long have you been taking this dose of medication (weeks)? If > 4 weeks on stable can proceed, if < 4 weeks exclusion but able to return once taking on stable dose for 4 weeks.

□L Past treatment or diagnosis of depression

□M Other, namely: text entry

-page break-

MEETS CRITERIA FOR PAST LIFETIME MDD IF KEY CRITERIA >=1 AND TOTAL SYMPTOMS >=5 OR self-reported diagnosis (46 and 47L)

MEETS CRITERIA FOR CURRENT MDD for exclusion from digital prevention trial IF IF KEY CRITERIA >=1 AND TOTAL SYMPTOMS >=5 AND PHQ-9 total score >=10

48: end of section – no depression

D. PHQ9 to assess depression

Over the last two weeks, how often have you been bothered by the following problems[4]?

	0 – Not at all	1 – Several days	2 – More than half the days	3 – Nearly every day
Little interest or pleasure in doing things.	◯	◯	◯	◯
Feeling down, depressed, or hopeless.	◯	◯	◯	◯
Trouble falling/staying asleep, or sleeping too much.	◯	◯	◯	◯
Feeling tired or having little energy.	◯	◯	◯	◯
Poor appetite or overeating.	◯	◯	◯	◯
Feeling bad about yourself, or that you are a failure, or have let yourself or your family down.	◯	◯	◯	◯
Trouble concentrating on things, such as reading the newspaper or watching TV.	◯	◯	◯	◯
Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual?	◯	◯	◯	◯
Thoughts that you would be better off dead or of hurting yourself in some way.	◯	◯	◯	◯

If answer to question 9 more than 0 then present the 3 risk questions:

R1 In the last 2 weeks have you been experiencing regular thoughts about suicide?

R2 In the last 2 week have you had any intention to hurt or kill yourself?

R3 In the last 2 weeks have you made any plans to hurt or kill yourself? [harm yourself or end your life?]

IF responses 1, 2 or 3, are selected for the above question then an in-the-moment automated message is provided giving advice and signposting including detailing a number of mental health supports specifically for suicidal thoughts or self-harm – to be adapted from risk messages from ECoWeB – To be adapted with student input;

if score includes PHQ9 -Q9>= 2 and yes to R2 or R3 at screening excluded from trial and signposted to relevant help re suicidality

Score for PHQ9 is total from items 1-9 giving a range of 0-27. There is a further question to ask about interference:

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

0	1	2	3
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
◯	◯	◯	◯

E. GAD7 to assess anxiety

Over the last two weeks, how often have you been bothered by the following problems?

	0 – Not at all	**1 – Several days**	**2 – More than half the days**	**3 – Nearly every day**
Feeling nervous, anxious, or on edge	◯	◯	◯	◯
Not being able to stop or control worrying	◯	◯	◯	◯
Worrying too much about different things	◯	◯	◯	◯
Trouble relaxing	◯	◯	◯	◯
Being so restless that it's hard to sit still	◯	◯	◯	◯
Becoming easily annoyed or irritable	◯	◯	◯	◯
Feeling afraid as if something awful might happen	◯	◯	◯	◯

5b. If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

0	**1**	**2**	**3**
Not difficult at all	Somewhat difficult	Very difficult	Extremely difficult
◯	◯	◯	◯

F. Warwick-Edinburgh Mental Wellbeing Scale

Below are some statements about feelings and thoughts. Please select the box that best describes your experience of each over the last two weeks.

	1 - None of the time	2 - Rarely	3 - Some of the time	4 - Often	5 - All of the time
I've been feeling optimistic about the future	◯	◯	◯	◯	◯
I've been feeling useful	◯	◯	◯	◯	◯
I've been feeling relaxed	◯	◯	◯	◯	◯
I've been dealing with problems well	◯	◯	◯	◯	◯
I've been thinking clearly	◯	◯	◯	◯	◯
I've been feeling close to other people	◯	◯	◯	◯	◯
I've been able to make up my own mind about things	◯	◯	◯	◯	◯

G. DEMOGRAPHIC QUESTIONS FOR ALL TRIALS – AT BASELINE

1. What is your current age? AGE_1

[Dropdown List]

16

17

18

19

20

21

22

23

24

25

26 and above

2a. How would you describe your gender? GENDER_1

Male

Female

Non-binary

Prefer to self-describe as: _____ [free text box] GENDER_TEXT_1

Prefer not to say

2b. Does your gender match the sex you were assigned at birth? GENSEX_1

Yes

No

Prefer not to say

3. How would you describe your sexual orientation? ORIENTATION_1

Heterosexual

Homosexual/Lesbian/Gay

Bisexual

Asexual

I do not use a label

Prefer to self-describe as: _____ [free text box] ORIENTATION_TEXT_1

Prefer not to say

4. How would you describe your ethnicity? ETHNICITY_1

Please choose ALL that apply: (1=YES, 2=NO)

Arab ARAB_1

Asian or Asian British – Indian INDIAN_1

Asian or Asian British – Pakistani PAKISTANI_1

Asian or Asian British – Bangladeshi BANGLADESHI_1

Chinese CHINESE_1

Other Asian background OTHERASIAN_1

Black or Black British – Caribbean CARIBBEAN_1

Black or Black British – African AFRICAN_1

Other Black Background OTHERBLACK_1

Gypsy or Traveller GYPSY_1

Mixed - White and Black Caribbean MIXEDWBC_1

Mixed - White and Black African MIXEDWBA_1

Mixed - White and Asian MIXEDWA_1

Other mixed background (please describe): [free text box] OTHERMIXED_1 (1=Yes, 2=No), OTHERMIXED_TEXT_1 (Text Response)

Other ethnic background (please describe): [free text box] OTHERETHNIC_1 (1=Yes, 2=No), OTHERETHNIC_TEXT_1 (Text Response)

White WHITE_1

Not known UNKNOWNETHNICITY_1

Prefer not to say PNSAYETHNICITY_1

5. Please describe your current student status with the university: STATUS_1

◯ Domestic (UK) student

◯ International student

IF International student is selected: INTERNATIONALCOUNTRY_1

What is your country of origin?

[Dropdown with alphabetical list of countries, including other option]

IF 'Other' is selected for country of origin then display:

Please name your country of origin:

[Free text box] COUNTRYTEXT_1

What level of degree are you studying? LEVEL_1

[dropdown]

Undergraduate

Postgraduate taught

Postgraduate research (MPhil/PhD)

Which subject are you studying? SUBJECT_1

[Free text box]

Are you studying full-time or part-time? FULLPARTTIME

[dropdown]

Full-time

Part-time

What is the duration of your course? COURSE_DUR_1 [answers coded 1 to 6]

1 year

2 years

3 years

4 years

5 years

6 years

Which year of your course are you currently in? PROJ_LEVEL_1 [answers coded 1 to 6]

Year 1

Year 2

Year 3

Year 4

Year 5

Year 6

Which of the following best describes where you are currently living? ACCOM_1

On /near to university campus (e.g. in your term time accommodation)

Away from university campus (e.g. at a parental home or elsewhere)

=IF on/near to campus ASK:

Which of the following describes your current accommodation? ACCOM_DL_1

I am living in accommodation arranged via the University

Away from university campus (e.g. at a parental home or elsewhere)

I am living in a privately-rented / owned house or flat (this could be a term-time address, or a permanent address)

Do you have a disability (including physical disability, blind or visual impairment, deaf or hearing impairment, dyslexia) or long-term health condition? DISABILITY_1. [yes = 1, no =0)

Yes

No

IF yes

[Display logic]

Could you please specify which disability or long-term health condition (Please tell us about all that apply). DISABILITY_TEXT_1

[free text box]

10. Have you **ever** been diagnosed with any of the following mental health conditions or learning difficulties? DIAGNOSIS_1

Please choose ALL that apply: (1= Yes, 0 =No)

I have never been diagnosed with a mental health condition or learning disability MENTALNONE_1

Mood disorder (e.g., Depression, Dysthymia, Bipolar Disorder) MOOD_1

Anxiety disorder (e.g., PTSD, OCD, Panic Disorder, Social Anxiety Disorder, Generalized Anxiety Disorder) ANXIETY_1

Psychotic disorder (e.g., Schizophrenia, drug-induced psychosis) PSYCHOTIC_1

Eating disorder (e.g., Bulimia Nervosa, Anorexia Nervosa, Binge Eating Disorder) EATING_1

Neurodevelopmental disorder (e.g. Autism Spectrum) NEURO_1

Sleep disorder (e.g., Insomnia) SLEEP_1

Substance use disorder (e.g., cannabis, alcohol) SUBSTANCE_1

Learning difficulty LEARNINGDIFF_1

ADHD ADHD_1

Other (please describe): _____ OTHERMENTAL_1 (code yes or no); OTHERMENTAL_TEXT_1 [for text entered]

*If YES to “I have never been diagnosed with a mental health condition or learning difficulty” is not selected

[Display Logic]

What age were your first diagnosed with a mental health condition? DMAGE_1

◯ Age 10 or younger

◯ Age 11-15 years

◯ Age 16 – 19 years

◯ Age 20 or older

G2. ADDITIONAL DEMOGRAPHIC QUESTIONS FOR ACUTE TRIAL (Question number indicates order to integrate in existing questions above)

11. In your lifetime, have you **ever** received treatment for a mental health condition? TREATMENTEVER_1. [YES =1, NO=0]

◯ Yes

◯ No

*If YES

[Display Logic]

What kind of treatment did you receive? TREATMENTEVERTYPE_1

◯ Medication

◯ Psychological (counselling or therapy)

◯ Both medication and psychological

12. In your **lifetime**, have you **ever** visited a hospital emergency department or been admitted to a hospital for help with a mental health condition? EMERGE_1

◯ Yes

◯ No

6. Have any of your first-degree blood relatives (e.g. biological parents or siblings) ever been diagnosed with any of the following mental health conditions or learning difficulties? RELATIVEHISTORY_1. (1 = YES, 0=NO, if any scored but FNONE_1 scored 1, and then specific score for each item)

Please choose ALL that apply:

Neither my biological parents or siblings have had a mental health diagnosis that I know of FNONE_1

Mood disorder (e.g. Depression, Dysthymia, Bipolar Disorder) FMOOD_1

Anxiety disorder (e.g. PTSD, OCD, Panic Disorder, Social Anxiety Disorder, Generalized Anxiety Disorder) FANXIETY_1

Psychotic disorder (e.g. Schizophrenia, Drug-related psychosis) FPSYCHOTIC_1

Eating disorder (e.g. Bulimia Nervosa, Anorexia Nervosa, Binge Eating Disorder) FEATING_1

Neurodevelopmental disorder (e.g. Autism Spectrum) FNEURO_1

Sleep disorder (e.g. Insomnia) FSLEEP_1

Substance use disorder (e.g., cannabis, alcohol) FSUBSTANCE_1

Learning difficulty FLEARNINGDIFF_1

ADHD FADHD_1

Other (please describe):_____ FOTHER_1 (code yes, no), FOTHER_TEXT_1 for text

Don't know FDONTKNOW_1

7. Please indicate the highest level of education attained by either of your parent/parent figures below: PEDUC_1

Did not complete high school/secondary school

Completed high school, secondary school or equivalent

Some post-secondary (college, university)

Completed post-secondary earning a certificate, diploma or bachelor's degree

Apprenticeship or trades certificate or diploma

Master's degree (MA, MSc)

Degree in a Profession (medicine, dentistry, veterinary medicine, law, engineering)

Doctorate degree (PhD)

Don't know

G3 CHILDHOOD LOSS

8a. Did your parents separate or divorce when you were a child or teenager? DIVORCE_1 (YES =1, NO = 0)

◯ Yes

◯ No

*If YES

[Display Logic]

What age were you when your parents separated or divorced? DIVORCEAGE_1

◯ 0-2 years

◯ 3-10 years

◯ 11-15 years

◯ 16-19 years

◯ 20 years or older

8b. Did you have a parent pass away when you were a child or teenager? LOSS_1 (YES =1, NO=0)

◯ Yes ◯ No

*If YES

[Display Logic]

What age were you when you experienced this loss? LOSSAGE_1

◯ 0-2 years

◯ 3-10 years

◯ 11-15 years

◯ 16-19 years

◯ 20 years or older

8c. Do you have experience of being in care? Being care experienced means you will have spent time living with foster carers under local authority care, in residential care (e.g., children's home), looked after at home under a supervision order, or in kinship care (where the local authority required you to live with a relative or friend), including special guardianship orders. FOSTER_CARE_1 (YES =1, NO =0, Unsure =2)

◯ Yes

◯ No

◯ Unsure

G4 EARLY ADVERSITY

9. In terms of difficult childhood experiences…

When you were a child or teenager was someone in your household very harsh, critical, or rejecting towards you? REJECTED_1. (yes =1 , no =0)

◯ Yes ◯ No

When you were a child or teenager were you ever hit repeatedly with an implement (such as a belt or stick) or punched, kicked or burnt by someone in the household[5]? HIT_1

◯ Yes ◯ No

When you were a child or a teenager were you physically or verbally bullied or teased very badly by peers? BULLIED_1

◯ Yes ◯ No

When you were a child or teenager did you ever have any unwanted sexual experiences?

◯ Yes ◯ No ◯ Unsure UNWANTEDSEXUAL_1

H. Measures to assess Stress

Perceived Stress Scale

Cohen S, Kamarck T, Mermelstein R. Perceived stress scale. Measuring stress: A guide for health and social scientists. 1994;10(2):1-2.

Thinking about stress, please indicate in the **last month**, how often have you...[10]

	Never	**Almost never**	**Sometimes**	**Fairly Often**	**Very often**
Felt that you were unable to control the important things in your life?	◯	◯	◯	◯	◯
Felt confident about your ability to handle your personal problems?	◯	◯	◯	◯	◯
Felt that things were going your way?	◯	◯	◯	◯	◯
Felt difficulties were piling up so high that you could not overcome them?	◯	◯	◯	◯	◯

-page break-

Over this past 3 months how would you rate the level of stress you generally felt related to:

	Not Stressful	Somewhat Stressful	Very Stressful	Extremely Stressful
Examinations (mid-terms, finals)	◯	◯	◯	◯
Managing my academic load	◯	◯	◯	◯
Maintaining my grades	◯	◯	◯	◯
Pressure to succeed	◯	◯	◯	◯
Adjusting to university life	◯	◯	◯	◯
Managing relationships (family, friends)	◯	◯	◯	◯
Social pressures (drinking, going out late, putting				

socializing before schoolwork)	○	○	○	○
Financial concerns (loans, debt, bills)	○	○	○	○
Managing self-care and health (eating healthy, exercising, hobbies)	○	○	○	○

In the past 3 / 12 months, have you had a relatively major bad experience in some aspect of your life other than the areas above (e.g., someone close to you dying; losing a job; serious illness or injury to yourself or someone close to you)?" BADEXPERIENCE

0 no 1 yes this happened to me once during this period 2 yes this has happened to me twice during the period, 3 yes this has happened to me more than twice - BADEXPERIENCEFREQ

If more than 0, ask to describe in text [BADEXPERIENCETEXT], and rate how stressful: not stressful, somewhat stressful, very stressful, extremely stressful [BADEXPERIENCESTRESS] (Scored 0=not stressful to 3 extremely stressful]

I. Work and Social Adjustment Scale W&SAS

Sometimes people have difficulty with certain day-to-day tasks because of stress, emotional difficulties or reduced mental wellbeing. Please look at each section and determine on the scale provided how much difficulty you have carrying out each activity because of stress, emotional difficulties or reduced mental wellbeing.

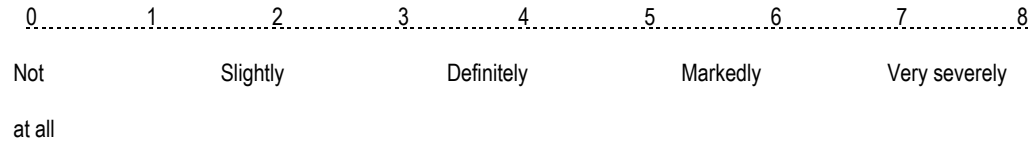
1. How difficult is **WORK (INCLUDING ACADEMIC STUDIES)** – if you choose not to have a job, please select N/A (not applicable)

0 ..... 1 ..... 2 ..... 3 ..... 4 ..... 5 ..... 6 ..... 7 8

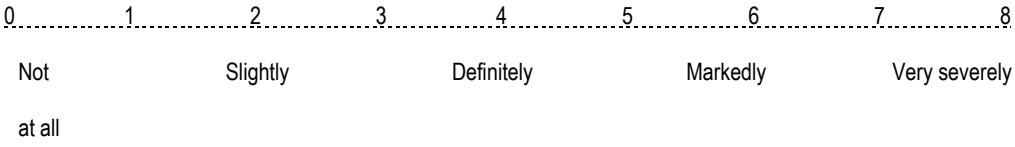
N/A

Not at all | Slightly | Definitely | Markedly | Very severely, I cannot work

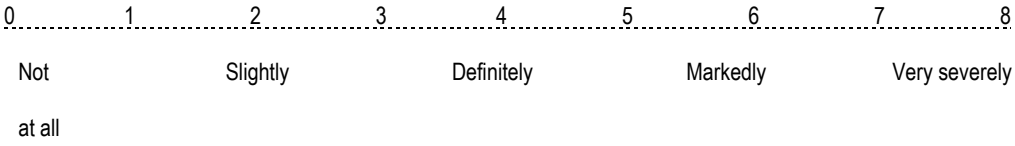
2. How difficult is **HOME MANAGEMENT** – Cleaning, tidying, shopping, cooking, looking after home/children, paying bills etc.



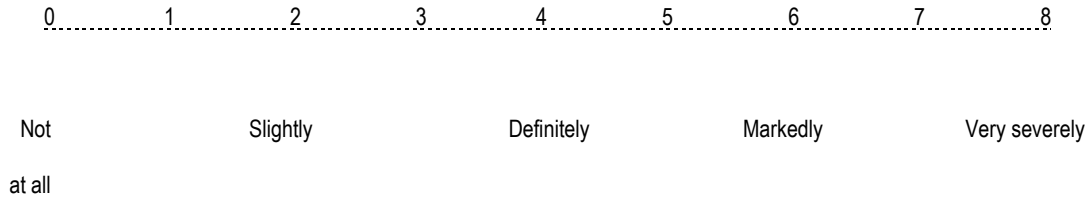
3. How difficult are **SOCIAL LEISURE ACTIVITIES** – With other people, e.g. parties, pubs, outings, sport, entertaining etc.



4. How difficult are **PRIVATE LEISURE ACTIVITIES** – **Done alone** e.g. reading, watching TV/films/streaming, music, social media, hobbies, exercise etc.



5. **How difficult are FAMILY AND RELATIONSHIPS** – Form and maintain close relationships with others including the people that I live with.



J. Brief Resilience Scale

Please indicate the extent to which you agree with each of the following statements by using the following scale: 1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, 5 = strongly agree.

	1 – Strongly Disagree	**2 - Disagree**	**3 - Neutral**	**4 - Agree**	**5 – Strongly Agree**
I tend to bounce back quickly after hard times.	◯	◯	◯	◯	◯
I have a hard time making it through stressful events.	◯	◯	◯	◯	◯
It does not take me long to recover from a stressful event.	◯	◯	◯	◯	◯
It is hard for me to snap back when something bad happens.	◯	◯	◯	◯	◯
I usually come through difficult times with little trouble.	◯	◯	◯	◯	◯
I tend to take a long time to get over setbacks in my life.	◯	◯	◯	◯	◯

K. Academic self-report and experience

Academic grades self-report

1.Does your academic course of study involve regular summative graded assessments and/or exams or is it assessed differently (e.g., thesis and viva)?

Yes, graded assessments and exams

No, other assessment

[logic if no to Q1 go to Question 5

2. What are your average subject grades for the last term/semester? 0-100% percent slider AVERAGEGRADES_1

3. What were your most recent end-term or exam grades for your main (principal) subject? 0-100% slider PRINCIPALGRADES_1

4. What grade are you hoping for / aiming for in your main subject? TARGETGRADES_1

0-100% percent slider

5. How satisfied are you with your academic progress over the last 3 months? Please rate the following statement: ACADEMICSATISFACTION_1

Overall, I am satisfied with my progress

Response options: Strongly disagree (-2) Disagree (-1) Neutral (0) Agree (+1) Strongly Agree (+2)

6. Have you missed any days from your studies because of illness, stress (e.g., including interruption)? Yes or No DAYSMISSED_1 (YES = 1, NO =0)

If yes, ask “How many days do you estimate that you have missed?” Number response option DAYSMISSEDNO_1

7. Have you been less productive because of stress or poor emotional wellbeing (e.g., trying to work but not concentrating well)? Yes or No LESSPRODUCTIVE_1 (YES = 1, NO =0)

If yes, ask “How many days do you estimate that you have been less productive?” Number response option. LESSPRODUCTIVENO_1

8. Have you missed any deadlines or failed to turn in any assignments during this last term/semester? Yes or No MISSDEADLINE_1

If Yes, how many? MISSDEADLINENO_1

L. PHQ-2 and GAD-2 in combined measure (in mediational analysis)

In the past 7 days, how often were you bothered by each of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious, or on edge GADPHQ_1	○	○	○	○
Not being able to stop or control your worrying GADPHQ_2	○	○	○	○
Little interest or pleasure in doing things GADPHQ_3	○	○	○	○
Feeling down, depressed, or hopeless GADPHQ_4	○	○	○	○

M. Cognitive and Behavioral Response to Stress Scale (CB-RSS) Miner et al., 2015 adapted CBRSSTOTAL

1. During the past 7 days in a stressful or upsetting situation:

How often did you take a moment to question your interpretation of what was happening when you got upset (e.g., look for a more positive or balanced explanation; weigh up different accounts, try and put things in perspective)? CBRSSQUESTFREQ_1

0	1	2	3	4	5	6
Never	**Rarely**	**Occasionally**	**Sometimes**	**Often**	**Very Often**	**Always**
○	○	○	○	○	○	○

(b) How helpful was this in making you feel better? CBRSSQUESTUSE_1

0	1	2	3	4	5	6
Not at all very helpful	**Slightly helpful**	**Somewhat helpful**	**Moderately helpful**	**Fairly helpful**	**Very helpful**	**Extremely helpful**
◯	◯	◯	◯	◯	◯	◯

2. During the past 7 days in a stressful or upsetting situation:

How often did you plan and/or do activities you knew you would enjoy? CBRSSPLANFREQ_1

0	1	2	3	4	5	6
Never	**Rarely**	**Occasionally**	**Sometimes**	**Often**	**Very Often**	**Always**
◯	◯	◯	◯	◯	◯	◯

How helpful was this in making you feel better? CBRSSPLANUSE_1

0	1	2	3	4	5	6
Not at all very helpful	**Slightly helpful**	**Somewhat helpful**	**Moderately helpful**	**Fairly helpful**	**Very helpful**	**Extremely helpful**
◯	◯	◯	◯	◯	◯	◯

During the past 7 days in a stressful or upsetting situation:

How often did you use relaxation or similar techniques to soothe, focus or calm yourself (e.g., meditation, breathing, focusing attention, imagery)? CBRSSRELAXFREQ_1

0	1	2	3	4	5	6
Never	**Rarely**	**Occasionally**	**Sometimes**	**Often**	**Very Often**	**Always**
◯	◯	◯	◯	◯	◯	◯

How helpful was this in making you feel better? CBRSSRELAXUSE_1

0	1	2	3	4	5	6
Not at all very helpful	**Slightly helpful**	**Somewhat helpful**	**Moderately helpful**	**Fairly helpful**	**Very helpful**	**Extremely helpful**

○ ○ ○ ○ ○ ○ ○

N. 2-item version of Self-Compassion Scale Short-Form
SELFCOMPASSION_1

"Please indicate how often you behaved in the stated manner during the past 7 days on a scale from 1 (Almost never) to 5 (Almost always).

	1 **Almost never**	2	3	4	5 **Almost always**
When I'm going through a very hard time, I give myself the caring and tenderness I need [SCS_1_1]	○	○	○	○	○
When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people [SCS_2_1]	○	○	○	○	○

O. Measure of treatment received or services used

1. Over the last 3 months, have you accessed any university provided wellness, counselling, mental health or learning support resources on campus or remotely? UNIVTREAT_1 (YES =1, NO=0)

◯ Yes

◯ No

*If NO [Skip Logic to Question 2]

Which College/University based wellbeing and mental health resource(s) did you access?

Select ALL that apply. [from drop down menu] IF SELECTED VALUE =1

__ Student Health Centre or a University affiliated GP (doctor)* UNIVGP_1

__ University Counselling service/Student Wellbeing service course of counselling or therapy* UNIVWELLBEING_1

__ Student urgent or crisis support (e.g., Student Intervention Team)* UNIVCRISIS_1

__ Academic or Personal Tutor* UNIVTUTOR_1

__ Welfare Deans* UNIVDEANS_1

__ Student Disability Service (University support for disabilities)* UNIVSDS_1

__ Student Occupational Health* UNIVOH_1

__ International Student Support* UNIVINTERNATIONAL_1

__ Chaplaincy* UNIVCHAPLAIN_1

__ Peer Support Service (examples include (but are not limited to) Peer Supporters, Nightline, welfare reps / welfare champions, Student Mentor Scheme)* Residential Support* UNIVPEER_1

__ Student Union / Student Guild (Representatives, Advice services)* UNIVGUILD_1

__ Sexual Harassment and Violence Support Service (e.g. Disclosure Response Team)* UNIVSHVSS_1

__Guild Societies[a] UNIVSOCIETIES_1

__Education Welfare team (support with studies, mitigation)*. UNIVEDUWELFARE_1

__Wellbeing groups[a.] UNIVGROUPS_1

__Self-help workbooks[a] UNIVWORKBOOKS_1

__Digital self-help e.g., online cognitive-behavioural therapy such as Silvercloud, Qwell, Sleepio)[a.] UNIVDIGITALSELFHELP_1

___Online counselling (e.g., Togetherall)[a.] UNIVONLINECOUNSELLING_1

__ Other (please specify):_____UNIVOTHER_1, UNIVOTHER_TEXT_1

For each element selected, follow-up questions ask (* if a person to see; [a] if a resource used by self):

*How many times have you seen or talked to someone from this service or resource (e.g., doctor, counsellor, therapist, support worker, tutor)? *Number response option*

[a]How many times did you use this resource? *Number response option*

AND

How much did this service or resource help with your specific problems? UNIVHELP_1

Made things a lot better 1, made things somewhat better 2, made no difference 3, made things somewhat worse 4, made things a lot worse 5

How satisfied are you with this service or resource? UNIVSATISFIED_1

Rate how much you agree with the statement - overall I was satisfied with the help received from this source

1 = strongly disagree, 2 = disagree 3 = neutral 4 = agree 5. = strongly agree

2. During the past 3 months, have you accessed any wellness, counselling, mental-health, self-help or other relevant support services external to the University? EXTERNALTREAT_1

◯ Yes

◯ No

*If YES [Display Logic], if No skip to question 3.

Which Non-College/University based resource(s) did you access to support your mental health?

Select ALL that apply.

__ GP or family doctor*. EXTGP_1

. *Nurse at GP surgery* EXTNURSE_1*

__ NHS IAPT service (e.g., CBT therapist, guided self-help, counselling)* EXTIAPT_1

__ NHS Secondary Care (e.g., Adolescent or Adult Mental Health Team; specialist service e.g., for eating disorders, psychiatrist)*. EXTSECONDARY_1

__ NHS Accident and Emergency[1] EXTAE_1

__ Overnight hospital stay[2] EXTHOSPSTAY_1

__ Private talking therapy / psychotherapy / counselling*. EXTPRIVTHERAPY_1

__ Mental Health Charity Service (for example, but not limited to: Samaritans, Shout, TogetherAll)[a] EXTCHARITY_1

__ Religious / Spiritual Guidance or Pastoral Care[b] EXTPASTORAL_1

__ Alternative therapy[b.] EXTALTERNATIVE_1

__Support from friends[a] EXTFRIENDS_1

__Support from family[a.] EXTFAMILY_1

__Self-help books[a.] EXTSELFHELP_1

___Online self-help e.g., app, website[a] EXTDIGITAL_1

Sexual Harassment, Abuse, and Domestic Violence Support Service[b] EXTSHADVSS_1

__ Other (please specify):_____EXTOTHER_1, EXTOTHER_TEXT_1

For each element selected, follow-up questions ask (matched by superscript):

*How many times have you seen or talked to this medical practitioner (e.g., doctor or psychiatrist) counsellor, nurse, or therapist? EXTPRACTITIONERNO_1

[2]How many nights have you stayed in hospital for a physical health difficulty? EXTPHYSHOSPITALNO_1

[2]How many nights have you stayed in hospital for a mental health difficulty? EXTMENTALHOSPITALNO_1

[1]How many times have you attended accident and emergency? EXTAENO_1

[a]How many times did you use this resource? EXTRESOURCENO_1

[b]How many times have you seen or talked to someone from this service or resource (e.g., religious/spiritual authority, support worker, therapist)? EXTTALKNO_1

AND

How much did this service or resource help with your specific problems? EXTHELP_1

Made things a lot better 1, made things somewhat better 2, made no difference 3, made things somewhat worse 4, made things a lot worse 5

How satisfied are you with this service or resource? EXTSATISFIED_1

Rate how much you agree with the statement - overall I was satisfied with the help received from this source

1 = strongly disagree, 2 = disagree 3 = neutral 4 = agree 5. = strongly agree

3. In the last 3 months, have you taken any medication for your mental health? MHMEDICATION_1

Yes (1)

No (2)

If Yes, name medication, entry in text box _____MHMEDICATION_TEXT_1

Over the past 3 months, how many weeks have you been prescribed this medication for your mental health? _____ MHMEDICATIONWKS_1

P. Physical health and lifestyle questions

1.a What is your approximate height?

____ft [free text box]. HEIGHT_FEET_1

____inches [free text box] HEIGHT_INCHES_1

1b. What is your approximate weight?

____lbs [free text box]. WEIGHT_LBS_1

BMI_1, BMIGRP_1 (1= Underweight (<18.5), 2= Normal weight (18.5-24.9), 3= Overweight (25-29.9), 4= Obese (>30); age and sex adjusted for students younger than 18)

2. How would you rate your overall physical health? PHYSHEALTH_1 (scored 1 to 5)

Please choose the appropriate response:

Very poor	Poor	Average	Good	Very good
○	○	○	○	○

3. During the **past month,** how much did problems with your physical health interfere with your day-to-day functioning? PHYSHEALTHINTERFERENCE_1 (scored 1 to 5, 5 – very severe interference)

- ○ No interference
- ○ Mild
- ○ Moderate
- ○ Severe
- ○ Very severe interference

In the past month…

4. a. How often have you worked out, gone to the gym, or attended a fitness class? EXERCISE_1 (scored never =0; 4+ = 4)

Never	Less than weekly	Once a week	2–3 times a week	4+ times a week
○	○	○	○	○

b. How often have you smoked tobacco or vaped? SMOKE_1 (scored Never =0 to 21+ = 4)

Never	Rarely	1–10 times a day	11–20 times a day	21+ times a day
○	○	○	○	○

c. How often on a typical day have you consumed a caffeinated beverage (coffee, tea, soda, and energy drinks)? CAFFEINE_1 (Scored Never =0, 4+ = 4)

Never	Less than once per day	Once a day	2–3 times a day	4+ times a day
◯	◯	◯	◯	◯

d. How often have you set aside time for self-care or recreation/hobbies (i.e., to relax, recharge, do something you enjoy, etc.)? SELFCARE_1. **(Scored Never =0, 4+ = 4)**

Never	Less than weekly	Once a week	2–3 times a week	4+ times a week
◯	◯	◯	◯	◯

Q. CIDI-SC – To assess co-morbidity

B9. Have you ever in your life had any of the following emotional problems? EMOPROBLEMS_1

	Yes	No
Depression	○	○
Manic-depression, mania, or bipolar disorder	○	○
Panic attacks	○	○
Problems with anxiety (nerves, worries, fears, compulsions, obsessions)	○	○
Any other serious emotional problem	○	○

E1. The next questions are about emotional difficulties you might have experienced at some time in your life.

(B9a = "YES": Earlier in the survey you reported having a history of depression. Think about a time in your life lasting 2 weeks or longer when you had the strongest feelings of this sort. During those 2 weeks, how often did you have each of the following experiences?/

ALL OTHERS ie. All other answers To B9A-E: Virtually everyone has times in their life when they feel sad, depressed, or discouraged about how things are going in their life. Think about a time in your life lasting 2 weeks or longer when you had the strongest feelings of this sort. During those 2 weeks, how often did you have each of the following experiences? *(If you are one of the few people that never had such times, mark "none of the time" to all the following questions.)*)

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time
Feel sad or depressed	○	○	○	○	○
Feel discouraged about how things were going in your life	○	○	○	○	○
Take little or no interest or pleasure in things	○	○	○	○	○
Feel down on yourself, no good, or worthless	○	○	○	○	○

CKPT.E2.

(E1a OR E1b = AT LEAST "MOST OF THE TIME") OR (E1c = AT LEAST "MOST OF THE TIME"), GO TO E2

E1a = “NONE OF THE TIME” AND E1b = “NONE OF THE TIME” AND E1c = “NONE OF THE TIME” AND E1d = “NONE OF THE TIME,” GO TO E7

ALL OTHERS GO TO E6

E2. During those 2 weeks, how often did you have each of the following experiences?

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time
Think a lot about death (either your own, someone else’s, or death in general)	○	○	○	○	○
Have trouble concentrating or making day-to-day decisions	○	○	○	○	○
Have a poor appetite or overeat	○	○	○	○	○
Have problems falling asleep, staying asleep, waking up too early, or sleeping too much	○	○	○	○	○
Talk or move more slowly than usual	○	○	○	○	○
Feel tired out, low in energy, or easily fatigued	○	○	○	○	○
Feel so low that it either caused distress or interfered with your activities at home, work, school, or in your social life	○	○	○	○	○

CKPT.E3.

(FIVE OR MORE RESPONSES IN (E1a OR E1b), E1c, E1d, E2a, E2b, E2c, E2d, E2e, E2f = AT LEAST “SOME OF THE TIME”) AND [(E1a OR E1b = AT LEAST “MOST OF THE TIME”) OR (E1c = AT LEAST “MOST OF THE TIME”)], GO TO E3 = history of MDE

ALL OTHER OUTCOMES FROM E1 and E2 GO TO E6

E3. About how old were you the very first time you had problems with (E1a = AT LEAST “MOST OF THE TIME”: sadness or depression/E1b = AT LEAST “MOST OF THE TIME”: feeling discouraged/ALL OTHERS FROM E1: taking little interest or pleasure in things) that lasted 2 weeks or longer? [i.e., some history of past MDE)

[DROPDOWN LIST] 4 or younger, 5, …, 35, 36 or older

E4. About how many different years in your life did you have problems like these that lasted 2 weeks or longer?

[DROPDOWN LIST] 1, 2, …, 35, 36 or more

E5. About how many months in the past 12 did you have problems like these?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E6.

E5 = 0, GO TO E7

ALL OTHERS FROM E5 GO TO E6

E6. In the past 30 days, how often did you have each of the following experiences?

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time
Feel sad or depressed	○	○	○	○	○
Feel discouraged about how things were going in your life	○	○	○	○	○
Take little or no interest or pleasure in things	○	○	○	○	○
Feel down on yourself, no good, or worthless	○	○	○	○	○

E7. (B9d = "YES": Earlier in the survey you reported having a history of anxiety. Think about a time in your life lasting 6 months or longer when you had the strongest feelings of this sort. During those 6 months, how often did you have each of the following experiences?/

ALL OTHERS FROM B9 (OR MAY BE SIMPLER IF B9d = no: Virtually everyone has times in their life when they feel worried or anxious. Think about a time in your life lasting 6 months or longer when you had the strongest feelings of this sort. During those 6 months, how often did you have each of the following experiences? *(If you are one of the few people that never had such times, mark "never" to all the following questions.)*

	Just about every day	More days than not	1-3 days a week	Less than 1 day a week	Never
Feel worried or anxious	○	○	○	○	○

Worry about a number of different things in your life, such as your work, family, health, or finances	○	○	○	○	○
Feel more worried than other people in your same situation	○	○	○	○	○
Worry excessively or too much	○	○	○	○	○

CKPT.E8.

E7a = AT LEAST “MORE DAYS THAN NOT” AND E7b = AT LEAST “MORE DAYS THAN NOT,” GO TO E8

E7a = “NEVER” AND E7b = “NEVER” AND E7c = “NEVER” AND E7d = “NEVER,” GO TO E14

ALL OTHERS FROM E7 GO TO E13

E8. During those 6 months, how often did you have each of the following experiences?

	Just about every day	More days than not	1-3 days a week	Less than 1 day a week	Never
Have trouble controlling your worry	○	○	○	○	○
Feel restless, keyed up, or on edge	○	○	○	○	○
Feel tired out, low in energy, or easily fatigued	○	○	○	○	○
Have difficulty concentrating or your mind going blank	○	○	○	○	○
Feel irritated, annoyed, or grouchy	○	○	○	○	○
Have muscle aches or tension	○	○	○	○	○
Have difficulty falling or staying asleep or have restless, unsatisfying sleep	○	○	○	○	○
Feel so upset that it either caused distress or interfered with your activities at home, work, school, or in your social life	○	○	○	○	○

CKPT.E9.

(E7a = AT LEAST “MORE DAYS THAN NOT”) AND (E7b = AT LEAST “MORE DAYS THAN NOT”) AND (THREE OR MORE RESPONSES IN E8b, E8c, E8d, E8e, E8f, E8g = AT LEAST “1-3 DAYS A WEEK”), GO TO E10

ALL OTHERS FROM E7 AND E8 GO TO E13

E10. About how old were you the very first time you had problems with worry and anxiety that lasted 6 months or longer?

[DROPDOWN LIST] 4 or younger, 5, …, 35, 36 or older

E11. About how many different years in your life did you have problems like these that lasted 6 months or longer?

[DROPDOWN LIST] 1, 2, …, 35, 36 or more

E12. About how many months in the past 12 did you have problems like these?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E13.

E12 = 0, GO TO E14

ALL OTHERS FROM E12 GO TO E13

E13. In the past 30 days, how often did you have each of the following experiences?

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time

Feel worried or anxious	○	○	○	○	○
Worry about a number of different things in your life, such as your work, family, health, or finances	○	○	○	○	○
Feel more worried than other people in your same situation	○	○	○	○	○
Worry excessively or too much	○	○	○	○	○

E14. (B9c = “YES”: Earlier in the survey you reported having a history of panic attacks. About how many panic attacks did you ever have in your life?/

ALL OTHERS from B9A-E OR B9C =”NO”: The next question is about panic attacks, also sometimes called anxiety attacks. These are sudden, strong feelings of fear or anxiety that reach their peak within a few minutes and are usually accompanied by physical reactions like racing heart, sweating, shortness of breath, feeling faint, or feeling sick to your stomach. People who have panic attacks sometimes feel like they might lose control, go crazy, or suddenly die. With this definition in mind, about how many panic attacks did you ever have in your life?) *(You can use any number between 0 and 999 to answer.)*

_____ NUMBER OF PANIC ATTACKS

CKPT.E15.

E14 ≥ 1 AND ≠ MISSING, GO TO E15

ALL OTHERS TO E14 GO TO CKPT.E23

E15. Which of the following problems do you usually have during these attacks? *(Check all that apply.)*

- ☐ A pounding or racing heart
- ☐ Sweating
- ☐ Trembling or shaking
- ☐ Shortness of breath
- ☐ Feeling like you might throw up
- ☐ Chest pain or discomfort

- ☐ Feelings of choking
- ☐ Feeling dizzy, light-headed, or faint
- ☐ Chills or heat sensations
- ☐ Numbness or tingling
- ☐ Fear of losing control or going crazy
- ☐ Fear of dying
- ☐ Feeling like things around you were unreal or like a dream
- ☐ Feeling like you were “not really there,” like you were watching a movie of yourself

CKPT.E16.

(E14 = 1 OR 2) AND (FOUR OR MORE RESPONSES CHECKED IN E15), GO TO E22

FOUR OR MORE RESPONSES CHECKED IN E15, GO TO E16

ALL OTHERS FROM E14 AND E15 GO TO CKPT.E23

E16. Attacks like these sometimes happen without provocation (“out of the blue”) and other times occur in situations where a person has a strong fear (e.g., a fear of heights or of snakes) or is in real danger (e.g., a motor vehicle accident). When did your panic attacks occur?

- ○ All of your attacks occurred without provocation (“out of the blue”)
- ○ Some of your attacks occurred “out of the blue” and others in situations where you had a strong fear or were in real danger
- ○ All of your attacks occurred in situations where you had a strong fear or were in real danger

CKPT.E17.

E16 = “ALL OF YOUR ATTACKS OCCURRED WITHOUT PROVOCATION,” GO TO E18

E16 = “SOME OF YOUR ATTACKS OCCURRED ‘OUT OF THE BLUE’ AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER,” GO TO E17

E16 = “ALL OF YOUR ATTACKS OCCURRED IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER,” GO TO E22

ALL OTHERS ON E16 GO TO CKPT.E23

E17. About how many “out of the blue” attacks did you ever have in your life? *(You can use any number between 1 and 999 to answer.)*

_____ NUMBER OF ATTACKS

CKPT.E18.

E16 = “SOME OF YOUR ATTACKS OCCURRED ‘OUT OF THE BLUE’ AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER” AND E17 = 0-2, GO TO E22

ALL OTHERS ON E17 GO TO E18

E18. (E16 = “SOME OF YOUR ATTACKS OCCURRED “OUT OF THE BLUE” AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER”: During the time when these “out of the blue” attacks were most severe or frequent, how often did you…/ALL OTHERS ON E16: During the time when these attacks were most severe or frequent, how often did you…)

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time
worry about having another attack?	○	○	○	○	○
avoid going certain places or doing certain things because you might have another attack or change your everyday activities to avoid having another attack?	○	○	○	○	○

CKPT.E19.

E18a OR E18b = AT LEAST “A LITTLE OF THE TIME,” GO TO E19

ALL OTHERS ON E18 GO TO E22

E19. (E16 = “SOME OF YOUR ATTACKS OCCURRED “OUT OF THE BLUE” AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER”: During the time

when these “out of the blue” attacks were most severe or frequent, how long did you worry about having another attack or change your behavior because of these attacks?/

ALL OTHERS ON E16: During the time when these attacks were most severe or frequent, how long did you worry about having another attack or change your behavior because of these attacks?)

- ○ Less than 1 month
- ○ 1-2 months
- ○ 3-5 months
- ○ 6-7 months
- ○ 8-12 months

E20. (E16 = “SOME OF YOUR ATTACKS OCCURRED “OUT OF THE BLUE” AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER”: About how old were you the very first time you had an “out of the blue” panic attack?/ALL OTHERS ON E16: About how old were you the very first time you had a panic attack?)

[DROPDOWN LIST] 4 or younger, 5, …, 35, 36 or older

E21. (E16 = “SOME OF YOUR ATTACKS OCCURRED “OUT OF THE BLUE” AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER”: About how many different years in your life did you have at least one of these “out of the blue” attacks?/ALL OTHERS ON E16: About how many different years in your life did you have at least one of these attacks?)

[DROPDOWN LIST] 1, 2, …, 35, 36 or more

NOTE: In the original World Mental Health College Student Survey, Question E22 asked: “About how many days out of 365 in the past year did you have one or more of these attacks?” This question was edited in the current version of the survey to instead ask about the number of months in the past year. These need to be converted to the same metric when doing analysis.

E22. (E16 = “SOME OF YOUR ATTACKS OCCURRED “OUT OF THE BLUE” AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER”: About how

many months in the past 12 did you have one or more “out of the blue” panic attacks?/ALL OTHERS ON E16: About how many months in the past 12 did you have one or more panic attacks?)

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E22a.

E22 = 1-11, GO TO E22a

ALL OTHERS ON E22 GO TO CKPT.E23

E22a. (E16 = “SOME OF YOUR ATTACKS OCCURRED “OUT OF THE BLUE” AND OTHERS IN SITUATIONS WHERE YOU HAD A STRONG FEAR OR WERE IN REAL DANGER”: About how many days in the past 30 did you have one or more “out of the blue” panic attacks?/ALL OTHERS ON E16: About how many days in the past 30 did you have one or more panic attacks)?

[DROPDOWN LIST] 0, 1, …, 29, 30

CKPT.E23.

B9b = “YES,” GO TO E24

ALL OTHERS ON B9 GO TO E23

E23. The next question is about whether you ever had an episode lasting 2 days or longer when your mood was much higher than usual most of the day, much more irritable than usual most of the day, or a mix of these things.

During these episodes, people are often much more excitable than usual, extremely self-confident, or optimistic. They often do things they would normally not do. And this sometimes gets them in trouble or puts them at risk of trouble.

With this definition in mind, did you ever in your life have an episode of this sort lasting 2 days or longer?

- ○ Yes
- ○ No

CKPT.E24.

E23 = “YES,” GO TO E24

ALL OTHERS ON E23 GO TO E34

E24. (B9b = “YES”: Earlier in the survey you reported having a history of manic-depression, mania, or bipolar disorder. Think about a typical intense episode lasting 2 days or longer when your mood was much higher than usual most of the day, much more irritable than usual most of the day, or a mix of these things./

ALL OTHERS ON B9 OR B9B = “No”: Think about a typical intense episode of this sort lasting 2 days or longer.) How much of the time during that episode…

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time
were you in a much better mood, much happier, or much more excitable than usual?	○	○	○	○	○
were you much more irritable or quick to take offense than usual?	○	○	○	○	
were you a lot more self-confident or optimistic than usual or believed you could do anything?	○	○	○	○	○

CKPT.E25.

E24a OR E24b = AT LEAST “SOME OF THE TIME,” GO TO E25

ALL OTHERS ON E24 GO TO E34

E25. How much of the time during that episode were you…

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time
much more active or energetic than usual?	○	○	○	○	○
much more hyper or wound up than usual?	○	○	○	○	○
much more engaged, busy, or productive than usual at school or work?	○	○	○	○	○
much more sociable or outgoing than usual?	○	○	○	○	○
much more involved than usual in thinking about or doing something sexual?	○	○	○	○	○

E26. How much of the time during that episode…

	All or almost all the time	Most of the time	Some of the time	A little of the time	None of the time
did you sleep much less than usual and still did not get tired or sleepy?	○	○	○	○	○
did you talk so much that other people couldn't get their say?	○	○	○	○	○
did thoughts race through your mind so fast you could hardly keep track of them?	○	○	○	○	○
did you have a hard time concentrating on what you were doing?	○	○	○	○	○
did you make bad decisions that could have caused problems for you?	○	○	○	○	○

CKPT.E27.

(E24a OR E24b = AT LEAST "SOME OF THE TIME") AND (ONE OR MORE RESPONSES IN E25a-e SERIES = AT LEAST "SOME OF THE TIME") AND (TWO OR MORE RESPONSES IN E24c, (E25a OR E25b OR E25c OR E25d OR E25e), E26a, E26b, E26c, E26d, E26e = AT LEAST "SOME OF THE TIME"), GO TO E27

ALL OTHERS (ON E24, E25, AND E26) GO TO E34 [i.e., default]

E27. About how old were you the very first time you had an episode of this sort that lasted 2 days or longer?

[DROPDOWN LIST] 4 or younger, 5, …, 35, 36 or older

E28. About how many different years in your life did you have an episode of this sort that lasted 2 days or longer?

[DROPDOWN LIST] 1, 2, …, 35, 36 or more

E29. What was the longest number of days in a row you ever had an episode of this sort?

_____ NUMBER OF DAYS

E30. How much did episodes of this sort ever interfere with your activities at home, work, school, or in your social life?

- ○ Extremely
- ○ A lot
- ○ Some
- ○ A little
- ○ Not at all

E31. How often during episodes of this sort did anyone notice or comment that you were much more energetic, wound up, productive, or outgoing than usual?

- ○ Often
- ○ Sometimes

- ○ Rarely
- ○ Never

E32. Were you ever hospitalized for one of these episodes?

- ○ Yes
- ○ No

NOTE: In the original World Mental Health College Student Survey, Question E33 asked: "About how many days out of 365 in the past year did you have an episode of this sort?" This question was edited in the current version of the survey to instead ask about the number of months in the past year. These need to be converted to the same metric when doing analysis.

E33. About how many months in the past 12 did you have an episode of this sort?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E33a.

E33 = 1-11, GO TO E33a

ALL OTHERS on e33 GO TO E34

E33a. Did you have an episode of this sort at any time in the past 30 days?

- ○ Yes
- ○ No

E34. Did you ever in your life have repeated attacks of anger when all of a sudden you lost control and either broke or smashed something, hit or tried to hurt someone, or threatened someone?

- ○ Yes
- ○ No

CKPT.E35.

E34 = “YES,” GO TO E35

ALL OTHERS ON E34 GO TO E36

E35. About how many months in the past 12 did you have one or more of these anger attacks?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E35a.

E35 = 1-11, GO TO E35a

ALL OTHERS ON E35 GO TO E36

E35a. Did you have one of these attacks at any time in the past 30 days?

- ○ Yes
- ○ No

E36. Did you ever in your life have times lasting 1 month or longer after an extremely stressful experience when you had frequent upsetting memories or dreams, felt jumpy, felt emotionally distant or depressed, or had trouble sleeping or concentrating?

- ○ Yes
- ○ No

CKPT.E37.

E36 = “YES,” GO TO E37

ALL OTHERS ON E36 GO TO E38

E37. During that month, how much were you bothered by the following reactions to any extremely stressful experience that ever happened to you?

	Extremely	A lot	Some	A little	Not at all
Avoiding external reminders of a stressful experience (e.g., people, places, conversations, activities, objects, situations)	○	○	○	○	○
Feeling distant or cut off from other people	○	○	○	○	○
Feeling irritable, having angry outbursts, or acting aggressively	○	○	○	○	○
Suddenly feeling or acting as if a stressful experience were actually happening again, as if you were actually back there reliving it	○	○	○	○	○

E37e. About how old were you the very first time you had reactions like these to any extremely stressful experience?

[DROPDOWN LIST] 4 or younger, 5, …, 35, 36 or older

E37f. About how many different years in your life did you have reactions like these?

[DROPDOWN LIST] 1, 2, …, 35, 36 or more

E37g. About how many months in the past 12 did you have reactions like these?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E37h.

E37g = 1-11, GO TO E37h

ALL OTHERS ON E37G GO TO E38

E37h. Did you have reactions like these at any time in the past 30 days?

- ○ Yes
- ○ No

E38. Did you ever have a time in your life when you were much more fearful, anxious, or shy than other people about being in social situations (e.g., meeting new people, attending a party, eating in public, talking to people in authority, speaking up in class)?

- ○ Yes
- ○ No

CKPT.E39.

E38 = “YES,” GO TO E39

ALL OTHERS on E38 GO TO E42

E39. How often do you try to avoid these social situations?

- ○ All or almost all the time
- ○ Most of the time
- ○ Some of the time
- ○ A little of the time

- ○ None of the time

E40. How much does your fear, anxiety, or avoidance of social situations ever interfere with your life?

- ○ Extremely
- ○ A lot
- ○ Some
- ○ A little
- ○ Not at all

E41. About how many months in the past 12 were you much more fearful, anxious, or shy than other people about being in social situations?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E41a.

E41 = 1-11, GO TO E41a

ALL OTHERS ON E41 GO TO E42

E41a. Did you have this fear or anxiety at any time in the past 30 days?

- ○ Yes
- ○ No

E42. Did you ever in your life have times lasting 3 months or longer when you had eating binges at least once a week; that is, your eating was out of control and you ate a very large amount of food over a short period of time (2 hours or less)?

- ○ Yes
- ○ No

CKPT.E43.

E42 = “YES,” GO TO E43

ALL OTHERS ON E42 GO TO E44

E43. About how many months in the past 12 did you binge eat at least once a week?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E43a.

E43 = 1-11, GO TO E43a

ALL OTHERS ON E43 GO TO E44

E43a. Did you binge eat at least once a week in the past 30 days?

- ○ Yes
- ○ No

E44. Did you ever in your life have times lasting 3 months or longer when you made yourself vomit, took laxatives, or did other things to avoid gaining weight after binge eating?

- ○ Yes
- ○ No

CKPT.E45.

E44 = “YES,” GO TO E45

ALL OTHERS ON E44 (I.E., E44= NO) GO TO NEXT SECTION

E45. About how many months in the past 12 did you make yourself vomit, take laxatives, or do other things to avoid gaining weight after binge eating?

[DROPDOWN LIST] 0, 1, …, 11, 12

CKPT.E45a.

E45 = 1-11, GO TO E45a

ALL OTHERS ON E45 GO TO NEXT SECTION

E45a. Did you do these things at any time in the past 30 days?

- ○ Yes
- ○ No

END OF SECTION

R. Suicidality

Thinking about your **past, have you ever**:

a. Wished you were dead or wished you could go to sleep and never wake up? NOTWAKEUP_1 (YES =1, NO =0)

◯ Yes ◯ No

b. Had thoughts about ending your life? ENDLIFE_1

◯ Yes ◯ No

c. Made any suicide attempts? SUICIDEATTEMPT_1

◯ Yes ◯ No

Hurt yourself on purpose without trying to end your life? SELFHARM_1

◯ Yes ◯ No

*If YES to “Have you hurt yourself on purpose without trying to end your life?”

[Display Logic]

How many times did you hurt yourself on purpose **in your entire life? SELFHARM_FREQ_1**

◯ 1-9 times ◯ 10-24 times ◯ 25 or more times

*If YES to any of above suicide/self-injury items display message re support options

S. Alcohol and drug use

1. How often do you have a drink containing alcohol? ALCOHOLFREQ_1 (scored Never =0, up to 4+ =4)

○ Never
○ Monthly or less
○ 2-4 times a month
○ 2-3 times a week
○ 4 or more times a week

2. How many standard drinks containing alcohol do you have on a typical day when drinking? TYPICALDAYDRINK_1 scored 0=I never drink to 5 = 10 or more

○ I never drink alcohol
○ 1 or 2
○ 3 or 4
○ 5 or 6
○ 7 to 9
○ 10 or more

3. How often do you have 5 or more drinks on one occasion? DRINKBINGE_1 (score 0 to 4)

○ Never
○ Less than monthly
○ Monthly
○ Weekly
○ Daily or almost daily

4. Thinking about the **past month**, how often have you used each of the following substances? SUBSTANCES_1. (scored never =0 to every or nearly every day =5) [total for all substances and individual item scores]

	Every or nearly every day	**3-4 days a week**	**1-2 days a week**	**1-3 days a month**	**Less than once a month**	**Never**
Cannabis (marijuana, pot, grass, hash, etc.) CANNABIS_1	○	○	○	○	○	○
Cocaine (coke, crack, etc.) COCAINE_1	○	○	○	○	○	○
Any other street drugs (e.g., opioids, LSD, speed, ecstasy) STREETDRUGS_1	○	○	○	○	○	○
Any prescription drug either without a doctor's prescription or more than prescribed to get high, buzzed, or numbed out (e.g., a stimulant, tranquilizer, muscle relaxant, or pain medication) PRESCRIPTION_1	○	○	○	○	○	○
Any non-prescribed medication to enhance academic performance (e.g., modafinil, stimulant medication) NONPRESCRIPTION_1	○	○	○	○	○	○

5. Has a relative or friend, doctor or other health worker been concerned about your substance use or suggested you cut down? SUBPROBLEM_1 (Both first yes = 1, second YES =2 NO =0)

○ Yes, but not in the past year

○ Yes, during the past year

○ No

*If YES

[Display Logic]

What substance(s) has relative or friend, doctor or other health worker been concerned about your substance use or suggested you cut down? Select ALL that apply. SUBPROBTYPE_1

(responses not mutually exclusive)) (1=Yes, 0=No)

- ○ Alcohol ALCOHOLPROB_1
- ○ Cannabis (marijuana, pot, grass, hash, etc.) CANNABISPROB_1
- ○ Cocaine (coke, crack, etc.) COCAINEPROB_1
- ○ Any other street drugs (e.g., opioids, LSD, speed, ecstasy) STREETDRUGSPROB_1
- ○ Any use of prescribed medication (stimulant, study drugs, pain killers) PRESCRIPTIONPROB_1
- ○ Other (please describe): _____ OTHERPROB_1 (1=yes, 2=no), OTHERSUB_TEXT_1 (free text)

T. Sleep

8. Thinking about a typical night in the last month…[11] SCI_TOTAL_1 (= total of all items, 0-32, Higher score= better sleep quality), SCIRE_1 (re-scaled 0-10), SCICLIN_1 (clinically significant symptoms; 1= ≤16, 0= >16)

a. How long does it take you to fall asleep? SLEEPTIME_1 (Scored 0-15 mins =4, >61 mins = 0)

0-15 minutes	16-30 minutes	31-45 minutes	46-60 minutes	≥61 minutes
○	○	○	○	○

b. If you wake up during the night … how long are you awake for in total? (add up all the awakenings) AWAKE_1 (scored 0-15 mins =4, >61 mins =0)

0-15 minutes	16-30 minutes	31-45 minutes	46-60 minutes	≥61 minutes
○	○	○	○	○

c. How many nights a week do you have a problem with your sleep? SLEEPPROBLEMFREQ_1 (score 0-1 =4, 5-7 =0)

0 – 1	2	3	4	5 – 7
○	○	○	○	○

How would you rate your sleep quality? SLEEPQUALITY_1 (score very good =4, very poor =0)

Very good	Good	Average	Poor	Very poor
○	○	○	○	○

Thinking about the past month, to what extent has poor sleep…[EACH ITEM SCORED 0 = Very much to 4=not at all]

	Not at all	A little	Somewhat	Much	Very much
Affected your mood, energy or relationships [SLEEPAFFECT_1]	○	○	○	○	○
Affected your concentration, productivity, or ability to stay awake [SLEEPCONCENTRATION_1]	○	○	○	○	○
Troubled you in general [SLEEPTROUBLE_1]	○	○	○	○	○

How long have you had a problem with your sleep? SLEEPDURATION_1 (Scored I don't have a problem =4, >1year =0)

I don't have a problem/ <1 month	1-2 months	3-6 months	7-12 months	>1 year
○	○	○	○	○

U. Social support/belonging /exclusion

Loneliness

1. **Please indicate how often each of the statements below is descriptive of you. LONELINESS_1 (TOTAL SCORE_**

	0 Never	1 Rarely	2 Sometimes	3 Often
How often do you feel that you lack companionship?	○	○	○	○

How often do you feel left out?	◯	◯	◯	◯
How often do you feel alone?	◯	◯	◯	◯
How often do you feel that you are no longer close to anyone?	◯	◯	◯	◯

The following questions have to do with how you feel about your life.

Please indicate on a scale from 1 (strongly disagree) to 5 (strongly agree) whether or not you experienced the following:

	1 – Strongly Disagree	2	3	4	5 – Strongly Agree
I have some friends/family members that usually encourage me	◯	◯	◯	◯	◯
I easily make others feel comfortable around me	◯	◯	◯	◯	◯
My friends always stick together	◯	◯	◯	◯	◯
I easily find new friends	◯	◯	◯	◯	◯
I have some close friends/family members that really care about me	◯	◯	◯	◯	◯
I am good at talking to new people	◯	◯	◯	◯	◯
I always have someone that can help me when I need it	◯	◯	◯	◯	◯
I always find something fun to talk about	◯	◯	◯	◯	◯
I always find something comforting to say to others when they are sad	◯	◯	◯	◯	◯
I have some close friends/family members that value my qualities	◯	◯	◯	◯	◯

V PERSONALITY MEASURES

1. Top 2 items of Emotional reactivity scale: top 2 items EMOREACTIVITY_TOT_1

"This questionnaire asks different questions about how you experience emotions on a regular basis. When you are asked about being 'emotional,' this may refer to being angry, sad, excited, or some other emotion. Please rate the following statements."

Each item is rated on a 0 to 4 scale (0=not at all like me and 4=completely like me).

I tend to get very emotional very easily. [EMOREACTIVITY_1_1]

Even the littlest things make me emotional. [EMOREACTIVITY_2_1]

2. Big Five Inventory-10 (BFI-10) Rammstedt & John (2007) journal of research in personality

English version. To measure neuroticism, agreeableness, conscientiousness, extraversion, openness

Instruction: "How well do the following statements describe your personality?"

Disagree Strongly	Disagree A little	Neither agree nor disagree	Agree a little	Agree strongly
1	2	3	4	5

I see myself as someone who …

… is reserved
… is generally trusting
….tends to be lazy
… is relaxed, handles stress well

….has few artistic interests
….is outgoing, sociable
….tends to find fault with others

….does a thorough job
….gets nervous easily
….has an active imagination

Scoring the BFI-10 scales:
Extraversion: 1R, 6; Agreeableness: 2, 7R; Conscientiousness: 3R, 8; Neuroticism: 4R, 9; Openness: 5R; 10 (R =item is reversed-scored).

Toronto Alexithymia Scale:

Choose one response that best describes how each item applies to you:

1. When I am upset I don't know if I am sad, frightened, or angry.

Strongly disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

2. I am able to describe my feelings easily.

Strongly disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

3. I find examination of my feelings useful in solving personal problems.

Strongly disagree Disagree Neither Agree nor Disagree Agree Strongly Agree

Rosenberg self-esteem measure: shortened to 2 items as per Tambs & Roysamb (2014):

Below is a list of statements dealing with your general feelings about yourself. Please indicate how strongly you agree or disagree with each statement.

Strongly disagree Disagree Agree Strongly Agree

1. I certainly feel useless at times.

2. I take a positive attitude toward myself.

Scoring:

Items 1,reverse scored. Give "Strongly Disagree" 1 point, "Disagree" 2 points, "Agree" 3 points, and "Strongly Agree" 4 points. Sum scores for all ten items. Keep scores on a continuous scale. Higher scores indicate higher self-esteem.

Brief measure of hopelessness (Brief-Neg-H measure):

“For each of the statements below, please tick the box that best applies to you.

1. The future seems to me to be hopeless and I can’t believe that things are changing for the better

Absolutely agree	somewhat agree	cannot say	somewhat disagree	absolutely disagree

2. I feel that it is impossible to reach the goals I would like to strive for

Absolutely agree	somewhat agree	cannot say	somewhat disagree	absolutely disagree

Relationship Questionnaire (Bartholomew & Horowitz, 1991, JPSP)

Adaptation of the attachment measure developed by Hazan and Shaver (1987)

4 short paragraphs describing the 4 attachment styles. Each respondent is asked to make ratings on a 7-point scale of the degree to which they resemble each of the 4 styles:

“Please read each of the descriptions of how you relate to others and rate how much each accurately resembles you.”

Secure. It is easy for me to become emotionally close to others. I am comfortable depending on others and having others depend on me. I don’t worry about being alone or having others not accept me. [SECURE_1]

How much do you resemble this style?

1	2	3	4	5	6	7
Not at all		A little		Moderately		Completely

Dismissive. I am comfortable without close emotional relationships. It is very important to me to feel independent and self-sufficient, and I prefer not to depend on others or have others depend on me. [DISMISSIVE_1]

How much do you resemble this style?

1	2	3	4	5	6	7
Not at all		A little		Moderately		Completely

Preoccupied. I want to be completely emotionally intimate with others, but I often find that others are as reluctant to get as close as I would like. I am uncomfortable being without close relationships, but I sometimes worry that others don't value me as much as I value them. [PREOCCUPIED_1]

How much do you resemble this style?

1	2	3	4	5	6	7
Not at all		A little		Moderately		Completely

Fearful. I am uncomfortable getting close to others. I want emotionally close relationships, but I find it difficult to trust others completely, or to depend on them. I worry that I will be hurt if I allow myself to become too close to others. [FEARFUL_1]

How much do you resemble this style?

1	2	3	4	5	6	7
Not at all		A little		Moderately		Completely

W. COGNITIVE ABILITIES

PROMISs Applied Cognition- Abilities scale. (Saffer et al., 2014) PROMIS_TOT_1

Please rate how well you feel you have been functioning on the items below over the past seven days.

Not at all /A little bit / Somewhat / Quite a bit / Very much

1 2 3 4 5

My mind has been as sharp as usual
My memory has been as good as usual
My thinking has been as fast as usual
I have been able to keep track of what I am doing, even if I am interrupted

X. Motivation to change

Miller & Johnson (2008) A natural language screening measure for motivation to change, 3-item version. Clients answered the questions with regard to a specified change goal that they were considering. Each item was rated on a Likert scale ranging from 0 to 10, with the following verbal labels beneath the numbers: Definitely Not (0–1), Probably Not (2–3), Maybe (4–6), Probably (7– 8), and Definitely (9–10). Item 1 reflects effort, item 2 reflects importance, item 3 reflects confidence:

Motivation to change:

“Please identify a specific change that would be a goal for this therapy for you, e.g., to feel less depressed, be more confident.

My change goal is _____” [CHANGEGOAL_TEXT_1]

Answer the following questions with regard to this goal.

1. I am trying to _”*input as answer above to my change goal*”_____. CHANGEEFFORT_1

Definitely Not (0–1), Probably Not (2–3), Maybe (4–6), Probably (7– 8), Definitely (9–10).

2. It is important for me to ___ *input as answer above to my change goal*”_____. CHANGEIMPORTANCE_1

_____.

Definitely Not (0–1), Probably Not (2–3), Maybe (4–6), Probably (7– 8), Definitely (9–10).

3. I could _____ *input as answer above to my change goal*”_____. CHANGECONFIDENCE_1

_____.

Definitely Not (0–1), Probably Not (2–3), Maybe (4–6), Probably (7– 8), Definitely (9–10).

Y. Self-control

Self-control: brief self-control scale Tangney et al 2004, using further analyses to distinguish two scales focused on impulsiveness versus restraint (first 3 items) (Maloney et al., 2012).

Items rated on a 5-point scale, anchored from 1 not at all like me to 5 very much like me: SELFCONTROL_1

Using the scale provided, please indicate how much each of the following statements reflects how you typically are.

	Not at all	Very Much
I wish I had more self-discipline	1--------2--------3--------4--------5	
I am good at resisting temptation	1--------2--------3--------4--------5	
I have a hard time breaking bad habits	1--------2--------3--------4--------5	
Sometimes I can't stop myself from doing something, even if I know it is wrong	1--------2--------3--------4--------5	
I do certain things that are bad for me, if they are fun	1--------2--------3--------4--------5	

Z. Therapy preference and expectancy: participants read and respond to the following.

"In the unguided version of the digital CBT therapy, you are given the option to work through online modules at your own pace and on your own. The content of these modules has been proven to successfully reduce anxiety and depression. The modules include education about anxiety and depression; about how mood, behaviours and thinking interact; plans and exercises to build up positive activities; lessons and exercises to practice identifying and challenging negative thinking. This information is provided in text, image, video, audio and quiz format."

How logical does this therapy seem to you? UNGUIDEDLOGIC_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

How complete does this therapy seem to you? UNGUIDEDCOMPLETE_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

How effective do you think this therapy would be for most people? UNGUIDEDEFFECTIVE_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

If a close friend or relative were depressed or anxious, would you recommend this therapy to them? UNGUIDEDRECOMMEND_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

To what extent do you think that this therapy would help you to understand the causes of your depression or anxiety? UNGUIDEDUNDERSTAND_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

To what extent do you think that this therapy would help you learn effective ways to cope with feeling depressed or anxious? UNGUIDEDCOPE_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

If you were to seek therapy, how likely would you be to choose this type of therapy?

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

If you were to try this type of therapy, how effective would it be in treating your depression and anxiety? UNGUIDEDEFFECTIVEME_1

1	2	3	4	5	6	7
1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

By the end of the therapy period, how much improvement in your symptoms do you really feel will occur? UNGUIDEDIMPROVEMENT_1

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

“In the guided version of the digital CBT therapy, you are given the option to work through online modules at your own pace and you are supported via communication with your therapist. The communication can include emails, telephone/video calls and messages within the treatment platform. The content of these modules has been proven to successfully reduce anxiety and depression. The modules include education about anxiety and depression; about how mood, behaviours and thinking interact; plans and exercises to build up positive activities; lessons and exercises to practice identifying and challenging negative thinking. This information is provided in text, image, video, audio and quiz format. The therapist can support you by checking up on your progress, encouraging you to do more, guiding you when you are stuck and answering your questions.”

How logical does this therapy seem to you? GUIDEDLOGIC_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

How complete does this therapy seem to you? GUIDEDCOMPLETE_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

How effective do you think this therapy would be for most people? GUIDEDEFFECTIVE_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

If a close friend or relative were depressed or anxious, would you recommend this therapy to them? GUIDEDRECOMMEND_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

To what extent do you think that this therapy would help you to understand the causes of your depression or anxiety? GUIDEDUNDERSTAND_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

To what extent do you think that this therapy would help you learn effective ways to cope with feeling depressed or anxious? GUIDEDCOPE_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

If you were to seek therapy, how likely would you be to choose this type of therapy? GUIDEDCHOOSE_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

If you were to try this type of therapy, how effective would it be in treating your depression and anxiety? GUIDEDEFFECTIVEME_1

1	2	3	4	5	6	7
Not at all	Low	Slightly	Neutral	Moderately	Very	Extremely

By the end of the therapy period, how much improvement in your symptoms do you really feel will occur? GUIDEDIMPROVEMENT_1

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

[first 4 questions focus on general credibility of therapy; second four questions focus on expectancy of personal improvement]

Attitudes towards Psychological Online Interventions (APOI), Schroeder et al., 2015, Journal of Affective Disorders

“The following statements deal with Psychological Online Interventions (otherwise known as computerised therapy or digital therapy, e.g., digital CBT self-help such as “Silvercloud”), which were developed to ameliorate emotional distress (e.g., depression or anxiety). Please state your personal appraisal or - if you are not familiar with such interventions from personal experience – please share

your expectations with us! Please rate your attitudes towards Psychological Online Interventions in general.

1. By using a psychological online intervention, I do not expect long-term effectiveness

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

2. It is difficult to implement the suggestions of a psychological online intervention effectively in everyday life

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

3. By using a psychological online intervention, I do not receive professional support

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

4. I have the feeling that a psychological online intervention can help me

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

5. A psychological online intervention can help me to recognize the issues that I have to challenge

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

6. I do not understand therapeutic concepts as well with a psychological online intervention as I do with a therapist

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

7. I learn skills to better manage my everyday life from a therapist rather than from a psychological online intervention

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

8. In crisis situations, a therapist can help me better than a psychological online intervention

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

9. By using a psychological online intervention I can reveal my feelings more easily than with a therapist

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

10. A psychological online intervention is more confidential and discreet than visiting a therapist

1 = totally agree, 2 = rather agree, 3 = not sure, 4 = rather disagree, 5= totally disagree

Problem description – variable name ProblemDescriptiontext

Participant asked in open text box to “Describe a current problem that you are facing – please use at least 3 sentences to describe the nature of the difficulty”"

Responses can be rated for:

Positivity-negativity; self-focus; abstract vs concreteness; -this will be done by raters to text

Therapy expectation (see in next column) –variable name TherapyExpectationtext

Participant asked to describe in open text box what they expect from therapy: “What do you expect from participating in this study and using this online therapy?”

(Problem-solving skills 2 items to solve from the Means Ends Problem Solving Task)

Instructions for student:

“You will be presented with two situations (stories). Please try to imagine yourself experiencing each situation (or story).

For each situation (or story), you will be given the beginning of the story – where there is a problem for you - and how the story ends – when the problem has been solved. Your task is to make up a story that connects the beginning that is given to you with the ending that is given to you. In other words, you are to provide a middle for each story that brings about the ending. Write the middle of the story in the textbox below each story.

Story 1: You get a message from your girlfriend (boyfriend) that she (he) is very angry with you because of something you have done. You do not want the relationship to break up. The situation ends when she (he) is very happy with you again. Begin the story when you get the message.

Open text box (variable name – relationshipMEPStext)

Story 2: You receive a note from your professor that you are likely to fail an important class in your major. If you do, you may have to reconsider your longtime career goal. The situation ends when you pass the class and are happy with your performance. Begin the story when you receive the note.

Open text box (variable name – professorMEPStext

Appendix C: Silvercloud Therapist Protocol
Getting Started

1. Participant will be randomly allocated Guided internet CBT or unguided internet CBT via CTU. Participant will accept and give consent to be contacted for Silvercloud.
2. Participant will be assigned onto Silvercloud system by therapist and set to guided support or unguided support. Silvercloud will automatically email client (both guided and unguided) with welcome email to sign up to the programme and to set their own password. When assigning participant for self-help there is no option to send message via Silvercloud.

a. Automated Silvercloud message (for guided condition only):

Hi [[client]]

Welcome to SilverCloud and congratulations on taking that big first step. I'm [[coach name]] and over the next few weeks, I'll be here to support you as we work through the [[programme]] programme together.

As your Coach, I will provide you with feedback and encouragement as you work through the modules and tools. We will have regular catch-up sessions together to guide you through applying the tools and techniques that you will learn through the programme.

However, your feedback is just as important - feel free to send me messages on the platform whenever you like; I will be able to read these on our scheduled catch-up sessions.

As you move through the programme, you have the option to share your activities with me. The more activities you share, the more helpful and relevant my feedback will be. We find that SilverCloud tends to work best with a 'little and often' approach, but you can use the programme at your own pace.

As a first step, I encourage you to spend some time getting used to the layout and content of SilverCloud. You can do this by checking out the first module in your programme.

Setting goals can also be a great way to put what you are learning into practice, so why not try setting yourself one or two goals for the coming week? Goals work best if they start simple so that you can build upon them later. For example, setting a specific time to log in each day, or a commitment to log in a certain number of times per week, are both simple and easily met.

I've set our first sesssion for [[review_date]]. You can book a different time and let me know your preferred way to meet (telephone or video call) here - ***(link to bookings with me).*** *Good luck this week and I look forward to working with you!*

Best Wishes[[coach]] on behalf of Nurture-U team

3. Therapist will send participant email from therapistnurture-u@exeter.ac.uk prompting to sign up following link on other email. Email will differ depending on guided vs unguided condition

a. Guided:

Hi [[client]],

I hope you are well.

My name is x.

I am a Psychological Wellbeing Practitioner working with the Nurture-U project at the University of Exeter. Thank you for showing an interest in our Nurture-U trials for student mental health and for completing the online assessment and consenting to join the trial. Based on that assessment, you are eligible to take part in our digital-based treatment called 'Space from Anxiety and Depression' using an online platform called SilverCloud.

I will be working with you as your Coach to support you through this process, and we will have regular catch-up sessions together to guide you through applying the tools and techniques that you will learn through the programme.

SilverCloud is a digital platform, based on Cognitive Behavioural Therapy (CBT) which has been proven to be effective in treating anxiety and depression. The programme consists of modules to provide you with an awareness of how your anxiety and low mood is maintained, along with tools and techniques to help you to feel better.

The more you practice and use the techniques in your daily life and not just when logged onto the digital platform, the more benefit you will see in your mood and the more your anxiety will reduce. You can work through these modules at your own pace at a time that suits you. We would recommend completing around 1 module per week to get the most out of the programme.

You should have received an email directly from SilverCloud to set up your account. Click the link in that email and it will take you to the sign-up page to set up your Silvercloud account with your own password. If you have not received this email from Silvercloud, check your Spam or junk folder. If you have still not received this email, please email therapistnurture-u@exeter.ac.uk and we will resend the link.

As a first step, I encourage you to spend some time getting used to the layout and content of SilverCloud. You can do this by checking out the first module called 'Getting Started'. Setting yourself some goals is a great way to put what you are learning into practice, so it may be helpful to create a couple of short-term goals that you would like to achieve in the coming weeks.

As your Coach, I will provide you with guidance, feedback, and encouragement as you work through the modules and tools. Please also feel free to send me messages and questions on the platform using the 'message' function whenever you like.

We typically have regular sessions via SilverCloud, usually every 2 weeks (up to 6 in total) to check up on how you are doing and review together what might be helpful for you to do next. We recommend having these regular sessions to get the most out of the therapy. The sessions can be scheduled via the platform itself; either online, (where I can give you written feedback on what you have done), via telephone or via video conferencing (Microsoft Teams), depending on your preference. Whenever we reach

the scheduled date for a session, I can see what you have done on the platform and give you advice and support that is tailored to you.

It would be great to arrange a first session with you to find out a bit more about what you are hoping to gain from the programme and how I can best support you.

To schedule our first session please follow this link and choose a suitable time slot for you ***(link to bookings with me) and let me know your preferred way to meet (telephone or video call).*** *After this initial consultation you have the option to continue review sessions over the phone or by video conference, or to receive written reviews from myself, which will be sent as a message in SilverCloud. As a starting point, there is already a scheduled review date of [review date] but this will change once you respond to me about your preferred availability.*

I look forward to supporting you with the programme. Please get in touch if you have any questions.

Kind regards,
[therapist]

b. **Unguided:**

Hi [[client]],

I hope you are well.

My name is x . I am a Psychological Wellbeing Practitioner working with the Nurture-U project at the University of Exeter. Thank you for showing an interest in our Nurture-U trials for student mental health and for completing the online assessment. Based on that assessment, you are eligible to take part in our digital based self-help treatment called 'Space from Anxiety and Depression' using an online platform called SilverCloud. You have been allocated to the self-directed version of the treatment, where you work through it on your own.

You should have received an email directly from SilverCloud to set up your account. Click the link in that email and it will take you to the sign-up page to set up your Silvercloud account with your own password. If you have not received this email from Silvercloud, check your Spam or junk folder. If you have still not received this email, please email therapistnurture-u@exeter.ac.uk and we will resend the link.

SilverCloud is an online programme to help improve mood and anxiety, based on the principles of Cognitive Behavioural Therapy (CBT). The programme consists of modules to provide you with an awareness of how your anxiety and low mood is maintained, along with tools and techniques to help manage your symptoms. Between engaging with the programme, we encourage you to practice the techniques in your everyday life. Engaging with the techniques outside of the programme is where you will see the change in your mood and anxiety happen.

As a first step, I encourage you to spend some time getting used to the layout and content of SilverCloud. You can do this by checking out the first module in your programme, 'Getting Started'. Setting yourself some goals can also be a great way to put what you are learning into practice, so it may be helpful to create a couple of short-term goals that you would like to achieve in the coming weeks.

This programme is designed to be worked through at your own pace. There are different modules that will be available to access, and we recommend completing these in order. We would recommend completing around 1 module per week to get the most out of the programme.

If you have any questions about how the treatment will work, or if you require further support, please do feel free to contact us via email. You can also access Silvercloud's own technical support via the platform.

Now it is over to you! Go ahead and sign-up via the email from SilverCloud and get started working through the programme.

If you have any queries, please contact us at therapistnurture-u@exeter.ac.uk.

Kind regards,
[therapist]

4. For guided only, participant replies and therapist books in call. Email sent confirming date and time of contact.

5. If no reply from participant within a week to send prompt email from [therapy email]

    a. **Prompt email if no contact (guided):**

    Hi [client],

    I hope you are well.

    I am just emailing as I have not heard from you following my previous email about setting up SilverCloud.

    [delete paragraph as appropriate]

    ***(If signed up but no response to booking email)** I can see you have signed up to Silvercloud and made a start, which is great. I have scheduled a review for [date} online so I can review how you have been doing on that date. I can support you in the therapy through a combination of scheduled telephone calls or scheduled video conference calls (Teams or Zoom) or written feedback within the platform. Please contact me to arrange a suitable date and time to do so. If I do not hear from you, I will go ahead with the scheduled review date and send you written online feedback within the Silvercloud programme.*

    ***(If not signed up/ no activity within 1 week)** I can see you have not signed up to Silvercloud and so I wanted to check if there was any way I can support you with getting*

started with your account. I have resent the welcome email from SilverCloud, which has the link to sign up. Please let me know if you would like to arrange a review by phone or video call so I can support you with getting started. Please let me know if you are having any difficulties accessing the platform or getting started.

If you have any queries, please email therapist-NurtureU@exeter.ac.uk.

K*ind regards,*

[therapist]

[**If patient has signed up and booked review but little progress on platform, this will be discussed at the review date around barriers/ difficulties with completing the modules, either synchronously or asynchronously through messaging in Silvercloud]**

b. Prompt email if no sign-up (unguided):

Hi [client]

I hope you are well and that everything is going ok. I can see that following my initial contact, you have not yet signed up to SilverCloud and so I wanted to check if there was any way I can support you with getting started with your account?

I have resent the welcome email from SilverCloud, which has the link to sign up but please do let me know if anything has come up for you which may have prevented you from engaging with the study so far. Please let me know if you are having any difficulties accessing the platform or getting started.

If you have any queries, please email therapist-NurtureU@exeter.ac.uk

All the best,
[therapist]

[These prompt emails can be repeated weekly up to 3 times]

6. **First contact review, 20 mins (video/telephone) [guided only]:**
   a. PWP introduces self and role
   b. Check if have accessed SilverCloud yet, if not resend invite email and ask if this has come through
   c. Discuss initial scores and current difficulties
   d. Risk assessment done if risk indicated and inform of risk protocols: follow Risk SOP
   e. Discuss client's goals and what they hope to get out of Silvercloud (SMART goals)
   f. Discuss the programme: overview content, guided self-help principles, review numbers and frequency of reviews (i.e., 4-6 sessions either weekly or fortnightly), discuss number of telephone/video check-ins which will be agreed with the patient
   g. Encourage to start with the content, recommend based on this

h. Agree on next video/phone call and send reminder on Silvercloud and if video send link to call
i. Send follow-up message on Silvercloud summarising the next steps:

Email below to be adapted as needed:

Hi xx

It was good to speak with you today. As discussed earlier, I'll be here to support you as we work through the 'Space from Depression & Anxiety' programme together. We agreed on xx (no. of sessions and frequency) online/over the phone/via Microsoft Teams.

As your Coach, I will provide you with guidance, feedback, and encouragement as you work through the modules and tools. However, your feedback is just as important – please send me messages before our next session so I can get a sense of how you are finding the programme and the techniques. This will allow me to offer more personalised feedback and guidance.

As you move through the programme, you have the option to share your activities with me. The more activities you share, the more helpful and relevant my feedback will be. We find that Silvercloud tends to work best with a 'little and often' approach, but you can use the programme at your own pace.

Before our next session, I recommend [overview modules to complete in this time]. Remember that the more you practice the techniques in your day-to-day outside of Silvercloud, the more progress you will make.

As agreed, I've set our next session date for xx via Silvercloud/phone/Teams. I am unable to view and respond to any messages within Silvercloud before this date so if you have any queries before then please email Therapist-NurtureU@exeter.ac.uk.

I look forward to speaking with you for your next review!

Kind regards,
XX

Follow Up Schedule (for guided only):

- 4-6 sessions (weekly or fortnightly – depending on client preference)
- Encourage client to write to PWP prior to each session using the programme function, the PWP will check every 1 or 2 weeks
- PWP will arrange video/telephone follow ups (at 4 sessions and then 6 or more frequent depending on client preference)
- Will check: Routine Outcome Monitorings (ROM), risk, Silvercloud progress
- Will message client on Silvercloud with progress/responding to any queries and comments
- Can use bank of messages available on separate document for the modules (e.g., boosting behaviour, managing worry, thought spotting and challenging)

If client misses/does not attend a review session then (a) provide feedback on progress in Silvercloud using messaging; (b) contact client within Silvercloud and by email to note that review session was missed and to seek to book another one. This to be attempted for up to 2 missing reviews.

Follow Up Schedule (for unguided only): [contingent on checking if has signed in and completed modules]

After two-to-three weeks since randomisation, email sent to participant:

a. if no sign-up (unguided):

Hi [client]

I hope you are well and that everything is going ok. I can see that following my initial contact, you have not yet signed up to SilverCloud and so I wanted to check if there was any way I can support you with getting started with your account?

I have resent the welcome email from SilverCloud, which has the link to sign up but please do let me know if anything has come up for you which may have prevented you from engaging with the study so far. Please let me know if you are having any difficulties accessing the platform or getting started.

If you have any queries, please email therapist-NurtureU@exeter.ac.uk

All the best,

[therapist]

b. If signed up but not completed modules: (to be adapted as necessary)

Hi [[client]],

I hope you are well.

It is great to see that you have signed up to the SilverCloud online treatment. However, I can see that you haven't worked through any of the modules yet.

SilverCloud is an online programme to help improve mood and anxiety, based on the principles of Cognitive Behavioural Therapy (CBT). You will get the most out of the programme if you try and complete around 1 module per week. I strongly encourage you to give it a try.

If you have any questions about the treatment, or if you require further support, please do feel free to contact us via email at therapist-NurtureU@exeter.ac.uk . You can also access Silvercloud's own technical support via the platform.

Kind regards,

[therapist]

c. If signed up and completed modules:

Hi [[client]],

I hope you are well.

It is great to see that you have signed up to the SilverCloud online treatment and are working your way through the modules. That's great progress. Well done. I hope that you are finding them useful and feeling better.

I recommend that you try as best you can to put what you are learning in the modules into practice in daily life. The more you use the skills and tools the more benefit you will get.

If you have any questions about the treatment, or if you require further support, please do feel free to contact us via email at therapist-NurtureU@exeter.ac.uk . You can also access Silvercloud's own technical support via the platform.

Kind regards,

[therapist]

Silvercloud video/telephone follow up (20 mins) (guided only):

1. PWP reintroduces self
2. ROM check in – ask pt to reflect on the changes (or lack thereof)
3. Risk check in (use Silvercloud to check in with this)
4. Programme check in – how have you been using the techniques? What have you noticed? What has been the impact so far?
5. Arrange follow up call

Silvercloud final review (20 mins) (guided only):

1. PWP reintroduces self
2. ROM check in – reflect on overall progress and get client input
3. Risk check-in (use SilverCloud check in to advise this)
4. Overall check in with progress and the programme, discuss how will continue to use the techniques and stay well for the future
5. If lack of progress therapist to signpost to university wellbeing service or local IAPT
6. Allow client to continue accessing SC after 3 months has ended to complete programme
7. Provide info for how to get in touch with other services if symptoms reoccur in the future

Ending Silvercloud

a. Ending Silvercloud – Guided (following final review, edit as necessary):

Hi X

It was good to speak with you today.

We have now completed (6) sessions and you have worked through various modules on the 'Space from Depression & Anxiety ' programme.

I would like to congratulate you on all your hard work and the progress you have made so far!

We have now come to the end of our work together, although you will be able to access the SilverCloud programme for up to a year to build on and remind yourself of what you have learnt on your own. This means I will not be able to leave feedback and you will not be able to leave messages for me.

I recommend that you complete the Staying Well tool to set ongoing goals, identify early warning signs and develop a personal plan of techniques that are helpful for difficult times.

I also suggest that you continue to set review dates with yourself, and review progress as we have done together. This can help to maintain progress and give you deadlines for your ongoing goals. You may find it helpful to use the questionnaires as a way of monitoring your mood, and I send some of these to you if you think it may be helpful.

You have done really well to complete the therapy and now you have several tools and techniques available to you to help manage your mood – I am confident that you can continue to use them to feel better and more confident moving forwards.

Thank you for your engagement with the therapy and I wish you all the best in the future!

Best wishes,

[therapist]

b. Ending Silvercloud – Unguided: [after 12 weeks since randomisation, edit as necessary]

Hi X

Well done on working through the 'Space from Depression & Anxiety ' programme over the last 12 weeks! I would like to congratulate you on all your hard work and the progress you have made so far!

You have now completed the 12-week period for the study. You will be able to access the SilverCloud programme for up to a year to build on and remind yourself of what you have learnt.

I recommend that you continue to use the techniques you have found most helpful and complete the Staying Well tool to set ongoing goals, identify early warning signs and develop a personal plan of techniques that are helpful for difficult times.

I also suggest that you continue to set aside time to check-in with how you are feeling. This can help to maintain progress and give you deadlines for your ongoing goals.

You have done really well to complete the programme and now you have several tools and techniques to help manage your mood – I am confident that you can continue to use them to feel better and more confident moving forwards.

Thank you for your engagement with the study and the programme and I wish you all the best in the future!

Best wishes,

[therapist]