

# Assessing and Enhancing Emotional Competence for Well-Being (ECoWeB) in Young Adults: A principled, evidence-based, mobile-health approach to prevent mental disorders and promote mental well-being



Trial Protocol Version 1.3 dated 05.07.21

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

Funded by: Horizon 2020-EU.3.1.2. - Preventing disease Record Number: 664247



**Table 1 Protocol Version Number and Date**

<b>Version</b>	<b>Date</b>	<b>Changes from previous version</b>
<b>0.1</b>	<b>29/11/2018</b>	<b>Based on HRA template as advised by sponsor</b>
<b>0.2</b>	<b>11/12/2108</b>	<b>Further work by LN</b>
<b>0.3</b>	<b>14/01/2019</b>	<b>LN adding in measures, materials and procedures</b>
<b>0.4</b>	<b>21/01/2019</b>	<b>Queries answered by EW, adding in latest materials</b>
<b>0.5</b>	<b>01/02/2019</b>	<b>Addressing comments by EW</b>
<b>0.6</b>	<b>12/02/2019</b>	<b>Editing by EW and LN and Appendices</b>
<b>0.7</b>	<b>18/02/2019</b>	<b>Consortium protocol</b>
<b>0.8</b>	<b>19/02/2019</b>	<b>MHRA review protocol draft</b>
<b>0.9</b>	<b>06/03/2019</b>	<b>MHRA submission protocol</b>
<b>1.0</b>	<b>23/04/2019</b>	<b>Post MHRA, separate info sheets</b>
<b>1.1</b>	<b>12.09.2019</b>	<p><b>Addition of insurance wording in section 13.9 (as requested by UOE Insurance team)</b></p> <p><b>Addition of pre-screening help pages in Appendix 16.1 (agreed in ethics application process, but had not been included in the ethics submission version (1) of the protocol.</b></p> <p><b>Increase of participant payment from £30 to a maximum of £60 page 7.1.3 to encourage recruitment and retention.</b></p> <p><b>Changes to the mode of data collection to now include the majority of assessment data being collected with Qualtrics (section 5 and 7).</b></p> <p><b>Reduction in measures in section 33 in light of analysis of the pilot study results to reduce the time burden on participants.</b></p>
<b>1.2</b>	<b>06.04.20</b>	<b>The trial protocol has been updated including COVID measures on page 43 and updated help text from the start of section 16.1.</b>
<b>1.3</b>	<b>05.07.21</b>	<b>Increase in sample size to compensate for technical problems with the intervention (the Monsenso app)</b>

**Table 2 Protocol Amendments**

<b>Amendment</b>	<b>Date</b>	<b>Changes from previous version</b>	<b>Date Authorised</b>
<b>1</b>	<b>23.10.2019</b>	<b>Post UK ethics with addition of insurance wording in section 13.9, also reduction in measures in section 33, and addition of pre-screening help pages in Appendix 16.1.</b>	<b>23.10.2019</b>

		Increase of participant payment from £30 to a maximum of £60 page 7.1.3. Change to assessment collection by the majority of the assessment data at baseline and follow ups being collected using Qualtrics (see section 5 and 7).	
2	06.04.20	<p>Editing of content and structure prescreening help pages in the light of expert advice</p> <p>Increased funding to pay participants up to £60 for taking part. This reward was originally going to be paid in Amazon Vouchers, but we have found out that payment with Love to Shop shopping vouchers will be easier to administrate.</p> <p>Feedback from our youth advisors indicated that certain minor wording changes and re-ordering of some information might better explain our procedures.</p> <p>We have advised participants in the information sheet that they need Wi-Fi or data to use the App.</p> <p>Addition of 2 questions relating to the impact of COVID-19 on ppts.</p>	
3		Our collaborator Monsenso informed us that they would be collecting personal information in the form of name and gender for their system to work. The data protection officer for the University of Exeter also changed. This necessitated small changes in the wording of our data protection and privacy policy.	03.06.20
4	03.08.2020	<p>The data protection form has been edited with tracked changes to remove reference to Qualtrics (our survey website provider) collecting participant IP addresses. This is because we have been able to work with Qualtrics to avoid the unnecessary collection of IP addresses. This necessitated the editing of a new data protection policy</p> <p>Our trial recruitment website (mymoodcoach.com) has now been created and connected to the Qualtrics survey system. Our recruitment website provides potential participants with the information sheet and study information including promotional videos and infographics before they take part so they are fully informed. The ethics committee were asked to review the website.</p>	
5	10.09.2020	The trial end date is now being extended because of delays starting recruitment. The new trial end date is expected to be September 2022 so this has necessitated changes in the	17/09/2020

		<p>information sheet, consent form and data protection and privacy policy.</p> <p>We have found out from our App developer that the App will only work on Android software version 8 or more so need to update our information sheet with this information.</p>	
6	25.03.21	<p>These amendments relate to work package 8 (WP8).</p> <p>As outlined in the original application (Task 8.1/8.2), in-depth, semi-structured interviews will be conducted with a self-selected sample of up to 50 young people participating in the trial across sites at 3-month follow up (from February 2021 onwards). The purpose of conducting the qualitative interviews is to broadly determine the barriers and facilitators to successful implementation of MyMoodCoach. A summary of the study protocol for WP8 is available in Appendix A.</p> <p>Changes have been made to the WP8 Consent Form and Information Sheet C (V0.8) for the 3-month follow-up interviews to reflect the revised WP8 protocol.</p> <p>The study protocol (Appendix A) also outlines details of an embedded sub-study (Task 8.3) with vulnerable or underserved groups. In addition to semi-structured interviews with trial participants at 3-month follow-up, semi-structured interviews will be also conducted with a sample of up to 30 young people from vulnerable or underserved groups, who are typically unrepresented in research or who are less likely to access services and interventions, not currently participating in the trial. The purpose of this study is to explore acceptability rather than efficacy of the intervention.</p> <p>A new Consent Form and Information Sheet D (V0.3) has been drawn up for the embedded sub-study.</p> <p>An updated Privacy Notice and Data protection Policy has been drawn up for WP8 for both the primary interview study (Form C V.01) and the embedded sub-study (Form D V.01)</p>	13/04/2021

		Finally, a risk management plan has been adapted from the original SOP for WP8 (WP8 Risk Management Plan V0.2 25.03.21).	
7	27.05.21	This amendment refers to work package 8 materials only. A section of text referring to the voice analysis was missed from their information sheet and data protection form so this has been corrected and new versions approved.	28.05.21
8	05.07.21	At the point that our original recruitment target of 2142 was recruited. Due to technical problems with the Monsenso app and its supporting server hosted by OVH, all participants were affected by the app being unavailable for approximately 1 month, badge (reward data) was out of date for many accounts for 2 months, and many Monsenso accounts were lost (some ppts started again on new accounts but some chose not to). As this was just after a major recruitment drive at all sites it is estimated that some 1500 participants were affected to varying degrees and this number had to be recruited again. Those that had already completed 1 and 3 month (primary outcome measure time point) follow ups were considered to have not been affected). Those recruited after the disruption were also considered not to have been affected. This amendment describes how that increase in sample size was calculated (increased from 2142 to 3600 plus) and how the analysis will be adapted to address the expected impact on our outcome data. Outcome data collection was collected on a separate system and therefore not directly affected by the data loss.	

**Assessing and Enhancing Emotional Competence for Well-Being (ECoWeB) in Young Adults: A principled, evidence-based, mobile-health approach to prevent mental disorders and promote mental well-being**

**ECoWeb: The Emotional Competence for Well-Being in Young Adults Study**

**RESEARCH REFERENCE NUMBERS**

University of Exeter CLES Ethics Committee reference: **eCLESPsy000048 v3.0**

**ClinicalTrials.gov Identifier:** NCT04148508

## 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:



Date:  
01/05/2019

Signature:

Name (please print): Ms Pam Baxter

Position: Senior Research Governance Officer

### Chief Investigator:

Signature:



Date:  
30/04/2019

Name (please print):

Edward Watkins.....

## KEY TRIAL CONTACTS

**Table 3 Key contacts**

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## ii. 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
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 <a href="#">Grant Agreement</a> )
DSUR	Development Safety Update Report
EAB	External Advisory Board
EC	Emotional Competence
ECom	European Commission
ECRF	Electronic Case Report Form
EU	European Union
Eudra CT	European Clinical Trials Database
GA	General Assembly
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
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

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 Control Trial
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAR	Serious Adverse Reaction
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	The University Of Exeter
LMU	Ludwig-Maximilians Uplattplniversitaet Muenchen
UGENT	Universiteit Gent
AUD	Audeering GMBH
UJI	Universitat Jaume I De Castellon
ICCS	Institute Of Communication And Computer Systems
MSS	Monsenso Aps
UOXF	The University Of Oxford
BUT	Vysoke Ucení Technické V Brně
FRAU	Fraunhofer Gesellschaft Zur Foerderung Der Angewandten Forschung E.V.
UNIGE	Universite De Geneve
UCPH	Kobenhavns Universitet
DJI	Deutsches Jugendinstitut Ev

### iii ECoWEB Project Summary

The European Commission funded ECoWeB project consists of consortium of academic researchers and technical collaborators who are conducting two major tasks:

- A new self-help app will be designed to improve wellbeing and prevent mental ill health in young adults
- This new app will be tested in the cohort randomised controlled ECoWeB study. Two randomised controlled trials called ECoWeB PROMOTE and ECoWeB PREVENT will be run from the ECoWeB study cohort.

Multiple academic partners (LMU, UGENT, UNEXE, UNIGE, ICCS) have worked together to create the content of the self-help app and technical collaborators MSS and AUD are hosting the app, and conducting audio analysis respectively. 4 academic sites will recruit for the trial (UNEXE, UJI, UGENT, LMU) and EXCTU will collect and store data on behalf of the UNEXE.

Although there are effective mental well-being promotion and mental illness prevention interventions for young adults, there is a need for more robust evidence on resilience factors, for more effective interventions, and for approaches that can be scalable and accessible at a population level. To tackle these challenges and move beyond the state-of-the-art, the ECoWeB project uniquely integrates three multidisciplinary approaches:

- (a) For the first time to our knowledge, we will systematically use an established theoretical model of normal emotional functioning (Emotional Competence Process) to guide the identification and targeting of mechanisms robustly implicated in well-being and general distress and psychopathology in young adults
- (b) A personalised medicine approach: systematic assessment of personal Emotional Competence (EC) profiles is used to select targeted interventions to promote well-being
- (c) Mobile application delivery to target scalability, accessibility and acceptability in young adults.

Our aim is to **improve mental health promotion** by developing, evaluating, and disseminating a comprehensive mobile self-help app to assess deficits in three major components of EC (production, regulation, knowledge) and to selectively augment pertinent EC abilities in adolescents and young adults. It is hypothesized that the targeted interventions, based on state-of-the-art assessment, will efficiently increase resilience toward adversity, promote mental well-being, and potentially act as primary prevention for mental ill-health. The EC intervention will be tested in cohort multiple randomized trials with young adults from many

European countries against a usual care control and an established, non-personalised socio-emotional learning digital self-help intervention. Building directly from a fundamental understanding of emotion in combination with a personalised approach and leading-edge digital technology is a novel and innovative approach, with potential to deliver a breakthrough in effective promotion of well-being and prevention of poor mental health.

**Table 6 Summary of Study**

Trial Title	Assessing and Enhancing Emotional Competence for Well-Being (ECoWeB) in the Young: A principled, evidence-based, mobile-health approach to prevent mental disorders and promote mental well-being	
Internal ref. no. (or short title)	ECoWeb: Emotional Competence for Well-Being	
Clinical Phase	III	
Trial Design	Phase III superiority parallel 3-arm randomised multicentre, multinational cohort randomized controlled trials (cmRCT)	
Trial Participants	European young adults (aged 16-22 years) in a population-oriented public health approach	
Planned Sample Size	2400 for overall cohort, (adjusted to 3600 plus after the technical difficulties).  Two trials are running within the one cohort.	
Treatment duration	Indefinite self-help app use by young people, anticipated main usage 1-2 months	
Follow up duration	Over 12 months (one month, three months, twelve months)  The primary time point is three months	
Planned Trial Period	24 months (starting recruitment to final follow up)	
	<b>RCTs &amp; measures</b>	<b>Outcome domains</b>
<b>Primary outcome</b>	ECoWeB-PROMOTE (PROMOTION of well-being and good mental health) – Mental Wellbeing (WEMWBS)  ECoWeB -PREVENT (PREVENTION of general distress, poor mental health and emotional disorders) - Depression (PHQ-9)	Indices of well-being and poor mental health
<b>Secondary outcomes</b>	Anxiety GAD-7  Functioning – WSAS  Health-related quality of life – EQ5D-3L  Health and social service use – ADSUS	Non-specific indices of poor mental health
Mediators	Emotional Competence	



	Assembled from multiple indices: rumination, appraisals, emotional knowledge and perception
Intervention	<p>Three intervention groups:</p> <ol style="list-style-type: none"> <li>1. Tailored Emotional Competence self-help delivered via app</li> <li>2. Self-help cognitive-behavioural approach app</li> <li>3. Usual practice and self-monitoring app (control).</li> </ol> <p>The active interventions are all entirely self-help and provide psychoeducation, tips, advice and strategies for well-being promotion.</p>
Route of Administration	Phone App (IOS and Android)

#### iv. FUNDING

**Table 7 Funding and Support in Kind**

<b>FUNDER(S)</b>	<b>FINANCIAL AND FINANCIALSUPPORT GIVEN</b>	<b>NON</b>
<b>Horizon 2020</b>	EUR 3 999 980	

**Table 8 Funding arrangements for the ECoWeB project:**

<b>Country</b>	<b>Organisation</b>	<b>Amount</b>
<b>UK</b>	UNIVERSITY OF EXETER	EUR 1 031 661,25
<b>Germany</b>	LUDWIG-MAXIMILIANS-UNIVERSITAET MUENCHEN	EUR 1 168 375
<b>Belgium</b>	UNIVERSITEIT GENT	EUR 561 681,25
<b>Germany</b>	AUDEERING GMBH	EUR 221 437,50
<b>Spain</b>	UNIVERSITAT JAUME I DE CASTELLON	EUR 307 312,50
<b>Greece</b>	INSTITUTE OF COMMUNICATION AND COMPUTER SYSTEMS	EUR 175 750
<b>Denmark</b>	MONSENSE APS	EUR 213 950
<b>UK</b>	UNIVERSITY OF WELLINGTON SQUARE, Oxford	EUR 227 431,25
<b>Czech Republic</b>	VYSOKÉ UČENÍ TECHNICKÉ V BRNĚ	EUR 15 000
<b>Germany</b>	FRAUNHOFER GESELLSCHAFT ZUR FÖRDERUNG DER ANGEWANDTEN FORSCHUNG	EUR 15 000
<b>Switzerland</b>	UNIVERSITE DE GENEVE	EUR 15 000
<b>Denmark</b>	ØBENHAVNS UNIVERSITET	EUR 15 000

Germany	DEUTSCHES JUGENDINSTITUT EV	EUR 32 381,25
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## **V. 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 European Commission. 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.

## **vi. ROLES AND RESPONSIBILITIES OF TRIAL MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS**

### **ECoWeB Project Work Packages:**

There are a number of work packages within the **ECoWeB project**, the **ECoWeB Cohort Study and Trials** forms work packages 6 and 7 of the overall project.

**Table 9 ECoWeB Project Work Packages**

<b>Work Packages</b>	<b>Responsibility</b>
WP1	Management and Project Coordination
WP2	Set-up of mobile app and website platform
WP3	Development of appraisal-focused intervention and assessment instruments
WP4	Development of rumination focused intervention and assessment instruments
WP5	Development of emotion perception and understanding assessment and intervention
WP6	Longitudinal Cohort: Set-up and Recruitment and Delivery
WP7	Cohort Multiple Randomised Trials
WP8	Implementation Science
WP9	Communication, Dissemination and Implementation of ECoWeB results

This trial protocol document focuses on governance and structure related to the conduct of the trials only. Details of the overall governance and structure of the ECoWeB consortium are provided in the Grant Agreement.

### **The ECoWeB Cohort Study and Trials**

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 ECoWeB Trial Management Group**

The Trial management group will oversee and manage the ECoWeB cohort study and ECoWeB randomised controlled trials and consists of the chief investigator, the ECoWeB project manager, the ECoWeB study manager, the statisticians, the data team and

representatives from the EXCTU management team. A subset of the group will meet weekly, with a monthly meeting to review progress and milestones.

**Table 10 Members of the Trial Management Group**

Name	Institution	Contact details
Lexy Newbold	UNEXE	<a href="mailto:a.newbold@exeter.ac.uk">a.newbold@exeter.ac.uk</a>
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### **The ECoWeB 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 Young Persons Lived Experience Group 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) would be a subgroup of the EAB with 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 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.

The TSC will responsible for monitoring serious adverse effects, protocol violations and any risks emerging from the trial (often duties of an independent Data Monitoring and Ethics Committee). It has the capacity to convene an independent Data Monitoring and Ethics Committee (DMEC) to conduct unblinded and interim analyses if concerned about serious adverse effects.

### **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. In the light of 1,2 & 3, to inform the funders (European Commission) on the progress of the trial;
4. To advise funders and Trial Management Group (ECoWeB Project Management Team) on publicity and the presentation of all aspects of the trial;
5. To determine if interim analyses of trial data should be undertaken and a DMEC needs to be convened
6. Consider any safety issues for the trial and recommend appropriate contingencies;
7. 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;
8. To ensure appropriate oversight of, and involvement in, trial management from lay advisers who have relevant lived experience.
9. To monitor data, risk and adverse outcomes in the trial.

**Table 11 Members of the TSC**

Name	Institution	Contact details
<b>INDEPENDENT MEMBERS</b>		
Independent Chair – Prof Cathy Cresswell	University of Oxford	c.creswell@oxford.ac.uk
Independent clinician/academic – Prof Chris Hollis	University of Nottingham	chris.hollis@nottingham.ac.uk
Independent clinician/academic		Jeremy Oliver
Independent statistician – Dr. Dennis Gorlich	WWU Munster	dennis.goerlich@ukmuenster.de
YAB members	TBA	
<b>TRIAL TEAM MEMBERS</b>		
Prof Ed Watkins as PI	UNEXE	e.r..watkins@exeter.ac.uk
Dr Lexy Newbold as trial manager	UNEXE	a.newbold@exeter.ac.uk
Prof Rod Taylor as lead statistician	EXCTU	r.taylor@exeter.ac.uk

### **ECoWeB External Advisory Board (EAB)**

The role of the EAB is to periodically review the progress and results of the project from a variety of angles and provide advice on ongoing and future work. The EAB will be composed of internationally renowned scientists, an expert in ethical issues and a representative from an association for young adult's mental health. 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 (iii) trial oversight (Trial Steering Committee - TSC). The EAB shall also assist and facilitate the strategic decisions

made by the GA and provide tactical recommendations on management, impact or methodology to the SC. The chair and membership of the EAB will set their terms of reference in liaison with the PMT. Potential members have been nominated and these have been approached for participation by the PMT. The EAB will meet at least annually (and six-monthly during the trial), either in person or via videoconference, and members will typically attend the General Assembly meetings. The EAB and associated TSC (for the trials within WP7) will include at least one member with a solid experience on ethical issues.

#### Role and Composition:

The EAB will be composed of internationally renowned scientists, one expert in ethical issues and a representative from an association for young people's mental health. All will be experts who are not affiliated with the project partners. The EAB will provide independent advice on (i) managing the project and maximizing its scientific, technological and health-related impact and (ii) the exploitation of the most promising results; (iii) and trial oversight (Trial Steering Committee). Meetings: The project's budget includes a line to cover the travel and subsistence costs of EAB members invited to attend project events. Each EAB member will be required to sign a confidentiality agreement. The Consortium Agreement will fix in detail the governance rules and procedures.

**Table 12 Members of the EAB**

Name	Institution	Contact details
Prof. Heleen Riper	Vrije Universiteit Amsterdam	<a href="mailto:h.riper@vu.nl">h.riper@vu.nl</a>
Prof. Helen Christensen	UNSW Sydney	<a href="mailto:h.christensen@blackdog.org.au">h.christensen@blackdog.org.au</a>
Dr. Dennis Gorlich	WWU Munster	<a href="mailto:dennis.goerlich@ukmuenster.de">dennis.goerlich@ukmuenster.de</a>
Prof. Ilina Singh	University of Oxford	<a href="mailto:alexandra.almeida@psych.ox.ac.uk">alexandra.almeida@psych.ox.ac.uk</a>
Prof. Moshe Zeidner	University of Haifa	<a href="mailto:zeidner@edu.haifa.ac.il">zeidner@edu.haifa.ac.il</a>
Dr. Nicola Bryom	King's College London	<a href="mailto:nicola.byrom@kcl.ac.uk">nicola.byrom@kcl.ac.uk</a>
Prof. Chris Hollis	University of Nottingham	<a href="mailto:chris.hollis@nottingham.ac.uk">chris.hollis@nottingham.ac.uk</a>

#### vii. Protocol contributors

This protocol has been written by the chief investigator and lead PI for the trial Professor Ed Watkins and trial manager Dr Lexy Newbold with the assistance of Dr Shelley Rhodes (senior trial manager) and Lynne Quinn (Operations Manager) from the University of Exeter Clinical Trials Unit. Tim Eames and Mary Davis (trial programmers) have contributed to the data management sections and Professor Rod Taylor (Exeter CTU Co-director) and Dr Fiona Warren (trial statistician) to the statistical analysis sections. The Youth Advisory boards from 4 countries were consulted on the processes and materials included (especially with respect

to informed consent, information sheets, trial recruitment, data protection) and initial feedback from the ethics committees of the 4 sites has also been incorporated.

#### **viii. KEY WORDS**

**Promotion, Prevention, Mobile App, Emotional Competence, Emotional resilience, Wellbeing**

#### **ix. TRIAL FLOW CHART**

The effect of the personalised self-help on EC, well-being, risk trajectories, general mental health difficulties, and social, educational, and occupational outcomes, will be evaluated using cohort multiple randomized controlled trials (cmRCTs; Relton et al., 2010). Eligible (healthy) individuals within the prospective cohort meeting relevant criteria will consent to be monitored for a year using a self-help app. Some of the cohort will be selected at random to be offered additional self-help elements within the app.

It is important to recognise that all participants in the cohort consent at the outset to provide data to be used to assess the benefit of the self-help apps for the outcomes of interest. In a cmRCT, a large observational cohort of participants meeting eligibility criteria is recruited (N) and their outcomes regularly measured. For each RCT, information from the cohort is used to identify all eligible participants (NA). Some eligible participants (nA) are randomly selected and offered the app with self-help components. The outcomes of these randomly selected participants (nA) are then compared with the outcomes of eligible participants not randomly selected; that is, for ECoWeB, those receiving usual practice plus the ECoWeB monitoring through the app (NA–nA).

The cmRCT design has multiple advantages:

- (i) it effectively combines a prospective long-term longitudinal cohort with a randomised trial(s): random selection of some participants is equivalent to random allocation of all with respect to generating 2+ groups whose selection and treatment have not been influenced by anyone or anything other than chance and where all known or unknown prognostic factors are distributed evenly at baseline, enabling strong inference about the causal effects of each intervention, whilst retaining key comparison groups that provide information as to the natural history of the condition and to usual care, essential for assessing primary prevention;
- (ii) consent to “try” a particular intervention is sought only from those offered that intervention, thus replicating the information and consent procedures that exist in routine health care;
- (iii) because individuals consent in advance to the option of having an intervention offered if eligible, we avoid individuals being knowingly allocated to a “lesser” usual care condition, enhancing recruitment and retention;
- (iii) there is the facility for multiple RCTs within one cohort;

(iv) increased efficiency and representativeness of the sample as longitudinal observational studies typically recruit a greater quantity and more representative sample of participants than RCTs;

(v) One goal is that this approach to explore EC will spark interest and dialogue about EC and mental health in young people generally, and communicate how EC is relevant to everyone on a continuum designed as a public health approach for the general population;

(vi) there is no re-use of data and permissions as the cmRCT approach requires that the original consent is for both participation in the cohort and potentially being offered an intervention.

The cmRCT design enables us to:

(i) examine the course of mental well-being and general mental health symptoms over time in higher-risk and lower-risk young people determined on their EC profiles, who are left to their own devices, providing a natural course “baseline” group to assess the trajectory of well-being and symptoms over time and its relationship to EC, and to (ii) test if mobile app based self-help designed to improve EC can change this trajectory. We thus simultaneously test: (a) a central assumption of the ECP model that deficits in EC at baseline will predict greater symptoms of poor mental health and reduced mental well-being at 3 and 12 months, controlling for baseline symptoms and well-being; (b) evaluate whether manipulating EC enhances outcomes, enabling strong causal inference.

The ECoWeb project will consist of 2 RCT's called ECoWeB-PROMOTE (indicating PROMOTION of well-being and good mental health) and ECoWeB-PREVENT (indicating PREVENTION of general distress, poor mental health and emotional disorders).

These trials share the same recruitment procedure, interventions, outcomes (including self-report measures of well-being, anxiety, and depression) and design. Both are interested in the promotion of well-being and the prevention of general poor mental health in young people. The key difference is whether the participants are deemed to be at higher or lower risk criteria for poor mental health based on their general emotional competence skills, i.e., for those at low risk, do the interventions further enhance well-being, for those at higher risk, do the interventions prevent the worsening of poor mental health, general stress and distress, as well as enhancing well-being. In all cases the recruitment procedure will be the same, but the inclusion and exclusion criteria are different and the primary outcome measures are different hence they are 2 trials, rather than one, all running within the same cohort.

The ECoWeB-PROMOTE trial will recruit participants not showing elevated risk on their EC profile. The ECoWeB-PROMOTE trial primarily aims to improve and maintain wellbeing in those that are relatively well. A range of indices of poor mental health and wellbeing will be used as outcome measures including wellbeing, depression, anxiety, and functioning: Because one index is needed for the primary outcome, wellbeing is the primary outcome measure as potentially most relevant and sensitive for a population that is relatively well.



The ECoWeB-PREVENT trial will recruit participants who have a hypothesized elevated risk of poor mental health based on their EC profile (although they are still well as we are excluding participants with current or past psychiatric disorders) with the primary aim of reducing that risk through the self-help app and promoting well-being (but not selected on clinical diagnoses or symptoms). A range of indices of poor mental health and wellbeing will be used as outcome measures including wellbeing, depression, anxiety and functioning: Because one index is needed for the primary outcome, depression symptoms have been selected as the primary outcome, as potentially the most sensitive and important index of poor mental health and distress, and as a strong predictor of future mental illness.

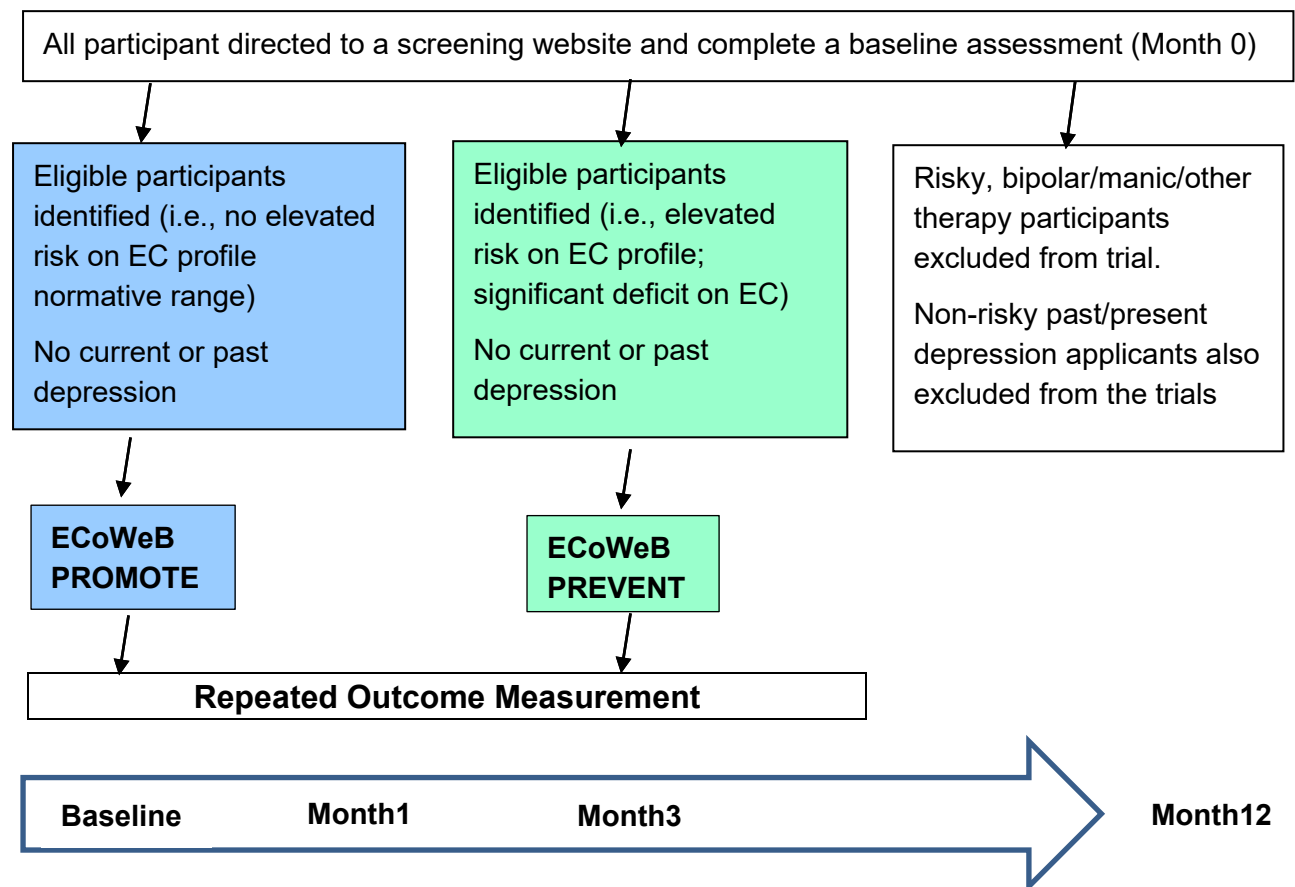
Elevated risk will be determined by an assessment of emotional competence (EC). Participants EC will be assessed by their scores on the emotional competence questionnaires that participants complete at their baseline assessment.

An algorithm is being developed to decide what combination of scores on the EC measures represent high and low risk, based on scoring in the least optimal quartile/tercile against normative data for this age group.

The remit for the Horizon2020 grant scheme is to work towards improving promotion of mental wellbeing and primary prevention of mental disorders, hence the ECoWeB-PREVENT and ECoWeB-PROMOTE trials exclude those with a history of past depression and current depression or a diagnosis of bipolar disorder or psychosis. The sample recruited will therefore be as inclusive as possible across the wider population of 16-22year olds and by definition are not a clinical population. This process is summarised in the following Figure 1:

**Figure 1: Illustration of cohort multiple randomised controlled trial (cmRCTs) as applied to ECoWeB**

**Large observational cohort of young adults recruited (n= 2400)**



In both trial participants are randomised into one of 3 conditions:  
 (1) Self-help app with CBT psychoeducation and strategies (Active control); (2)  
 (Personalized EC self-help app; (3) Usual practice including self-monitoring app  
 only (control) All interventions accessed on an App. Estimated length of App use 6 weeks

## 1 BACKGROUND

The ECoWeB project aims to develop, evaluate, and disseminate a comprehensive mobile web-based application (app) to assess deficits in three major components of Emotional Competence (EC; production, regulation, and knowledge) and to then provide engaging, personalised self-help to augment pertinent Emotional Competences in adolescents and young adults. It is expected that the targeted self-help, based on state-of-the-art assessment, motivation technologies, and EC training, will efficiently increase resilience toward adversity and promote mental well-being. The self-help app therefore targets non-medical conditions such as emotional competence skills, non-specific stress and emotional health and well-being. The program will be tested in 2 trials (preventing worsening general mental health in those at higher risk; a well-being promotion trial in those at lower risk) stratified within a large longitudinal cohort with participants from across Europe, against a usual practice control and a non-personalised self-help digital intervention based on well-established socio-emotional and cognitive-behavioural intervention principles. The project team involves 13 institutions including 2 small and medium enterprises (SMEs) across 8 European nations (UK, Germany, Belgium, Spain, Greece, Czech Republic, Denmark, Switzerland) permitting access to a diversity of young Europeans.

Mental and emotional well-being is essential for an individual's adaptive functioning and development, educational, occupational, and interpersonal settings. The ECoWeB project addresses an **important public health need** because resilience and mental well-being are critical factors influencing mental and physical health, and family and workplace functioning. Individuals who exhibit low resilience and poor emotion regulation skills are disproportionately likely to develop mental health disorders such as anxiety and depression in the wake of stress, whereas high resilience is associated with improved mental well-being and quality of life, better interpersonal and family functioning, enhanced educational and work performance, and improved physical health (Connor & Davidson, 2003; Davydov et al., 2010). Disorders such as anxiety and depression are extremely debilitating for individual academic and occupational career trajectories as well as family and social relationships, and for society as a whole, incurring substantial health and social care costs and loss of productivity. There is growing global concern about the trend for ever earlier onset of mental disorders that severely affect the life chances of young adults at a key formative period, leading to an urgent call for prevention work (WHO report, Marcus et al., 2012; Patton, 2016). The incidence of anxiety and depression markedly increases from mid-adolescence through to young adulthood, peaking during this period (Kessler et al., 2005). First onset at this age predicts a long-term trajectory of symptoms into adult life (Thapar et al., 2012), with early mental health difficulties having a significant long-term negative impact on future health, education, employment, and social outcomes (Kessler et al., 2005; Mehta et al., 2015; Thapar et al., 2012). Moreover, absence of mental illness does not mean presence of mental health: Reduced mental well-being ("languishing") even when below the threshold for a mental disorder is an important outcome as it is associated with increased distress and impaired productivity, whereas elevated well-being ("flourishing") predicts better productivity, psychosocial functioning and

health (Keyes, 2007). Preventing poor mental health and improving mental well-being are thus key parallel strategic priorities for young adults (Royal College Psychiatrists, 2010; Mehta et al., 2015).

## **2 RATIONALE**

Although there are evidence-based primary prevention programmes for children, adolescents and young adults, including Social-Emotional Learning programmes (SEL; Durlak et al., 2011), whole-school anti-bullying programmes, and cognitive-behavioural approaches (Clarke et al., 2015a), there is considerable scope to improve the efficacy and accessibility of mental health prevention and promotion. A number of recent systematic reviews of mental health prevention and promotion for youth including Cochrane reviews (Clarke et al., 2015a,b; Hetrick et al., 2016; Merry et al., 2011; Schulte-Körne & Schiller, 2012; Stockings et al., 2016) conclude that school-based interventions and online interventions, typically utilising cognitive-behavioural approaches, can successfully promote youth resilience and mental health, although effect sizes are relatively small, and selective interventions may do better than universal interventions. A major limitation is that most evidence-based interventions require considerable person-hours because of the time to train and supervise the relevant workforce (e.g., therapists, teachers) in the intervention as well as the intervention delivery time, which limits scalability, except perhaps if implemented as part of the normal school curriculum. Major remaining challenges include: (i) to develop appropriate assessment procedures for targeted risk factors; (ii) to personalize interventions based on assessment results; (iii) to improve intervention efficacy; (iv) to scale up evidence-based interventions to a population level, without numbers being constrained by needing a delivery workforce (e.g. therapist/teacher) or by settings and infrastructure that not everybody can or will access (e.g. school); (v) to increase engagement for young adults with the greatest health and social inequality problems, e.g., disadvantaged and minority groups, refugees, and migrants. In addition, there is increasing evidence for a high degree of comorbidity between mental disorders such as depression and anxiety (Cummings et al., 2014; Nolen-Hoeksema & Watkins, 2011; Scherer & Mehu, 2015). The traditional psychiatric approach has tended to treat these emotional dysfunctions as separate classes with different diagnostic categories and treatment options.

As a critical advance on the state-of-the-art, we propose that many of the interrelated disorders and accompanying risk factors have a common root in the malfunctioning of emotion mechanisms and insufficient Emotional Competence (EC) to resiliently deal with the impact of minor and major life events (see also Bylsma et al., 2008). We hypothesize that good EC functioning, including better abilities to perceive and understand emotions and emotional situations to regulate one's own emotion, will be associated with reduced internalizing difficulties (symptoms of anxiety, depression, low self-esteem, non-specific stress) and reduced externalizing difficulties (aggression, impulsive behaviours, alcohol/substance abuse).

We will apply a comprehensive, integrated, and theory-based approach to assessing risk factors, building resilience, and applying appropriate prevention/promotion interventions. In response to the urgent call for prevention programs highlighted by the WHO report (Marcus et al., 2012), we focus on the development and validation of assessment procedures to identify major EC-related risk factors for poor mental health, reduced well-being and resilience, and impaired development, as well as of corresponding prevention interventions for adolescents and young adults. Because of the range of underlying mechanisms and individual differences, we advocate a personalisation approach involving systematic assessment of personal EC profiles to select targeted interventions. Given the need for time- and resource-effective interventions that can reach large volumes of young adults across European countries, we plan mobile app-based delivery of self-help, corresponding to young adult's lifestyles. Potential advantages of self-help digital interventions include: they are autonomous, do not require a workforce to deliver, making them highly scalable at low cost; they are integrated into daily life with advantages for changing habitual patterns of response; and they have high levels of use and engagement in young adults (Munoz et al., 2015; Schueller et al., 2013), for example, over 90% of 16-24 year olds in UK and Germany have a smartphone (IZI, 2017; Ofcom, 2015).

To tackle the key challenges identified above, ECoWeB will uniquely and innovatively integrate: (i) a theory driven approach that focuses on explicitly targeting identified EC mechanisms implicated in well-being and psychopathology; (ii) a personalisation approach offering each individual a set of self-help psychoeducation, tips, advice and strategies matched to their EC profile; (iii) mobile health digital delivery to target scalability, accessibility, and acceptability in young adults (Baños et al., 2017; Fleming et al., 2016; Mohr et al., 2014; Munoz et al., 2015). We take an international and interdisciplinary approach to promoting mental well-being in the young, incorporating strong stakeholder and young person involvement. Central to our approach is that interventions need to build on basic theoretical and empirical understanding of how individuals cope with emotional distressing situations, how they manage their emotions, and how this can be enhanced. To our knowledge, this will be the first systematic attempt to use an established theoretical model of normal emotional functioning (Emotional Competence Process model, ECP; Scherer, 2007) in order to assess young adults at risk for poor mental health and reduced well-being and resilience and translate knowledge of EC into better mental health promotion.

## CONCEPT AND METHODOLOGY

**Overall Concept.** Our concept is based on the effective and ground-breaking integration of basic science in EC with a personalised approach that uses Behavioural Intervention Technologies (BITs, Schueller et al., 2013) to enhance the delivery of interventions.

**Emotional Competence:** The central hypothesis of the ECoWeB project is that EC causally influences mental wellbeing and mental health, and, therefore that training relevant EC skills

(especially where there is an identified deficit) will lead to general benefits in mental well-being and mental health. There is considerable empirical evidence that lack of Emotional Intelligence (EI) is associated with low levels of mental well-being, poor functioning, and increased incidence of mental disorder, whereas high EI is associated with resilience and well-being (meta-analyses by Martins et al. 2010; Sánchez-Álvarez et al., 2016; Schutte et al. 2007; Hall et al. 2009). Recently, Zeidner et al. (2012) reviewed the evidence for EI and concluded that further progress in the direction of ability models (e.g., MacCann & Roberts, 2008; Mayer et al. 2003) is desirable, particularly with respect to the development of emotional competences (Saarni, 1999). Relatedly, meta-analyses have confirmed that lack of EC, such as less effective expression and understanding of emotions, is associated with increased anxiety (Mathews et al., 2016) and externalizing problems in youth (Trentacosta & Fine, 2010). Impaired emotional regulation skills are associated with increased psychopathology (Sheppes et al. 2015), with emotional regulation strategies shown to modify emotional outcomes in experimental studies (Webb et al. 2012). Reflecting this recommendation, ECoWeB adopts one well-developed ability model, the Emotional Competence Process model (ECP; Scherer, 2007), which is based on an empirically validated theoretical process model of emotion (Component Process Model, Scherer, 2001), that draws on established findings about the mechanisms underlying normal and successful through to maladaptive emotional functioning (Mehu & Scherer, 2015). The ECP model distinguishes 3 EC component processes (abilities), which are all implicated in mental well-being and mental health:

- (1) **Appropriate emotion production** requiring an appropriate self-image and accurate **appraisal** of emotion eliciting events, including appraisals of their causes and of one's control over their potential consequences. The prerequisite for accurate appraisal is to evaluate each event on its merits (with respect to the event: its novelty or expectedness, its value, its goal conduciveness, its causation; and with respect to one's coping ability, such as control and power) and to avoid being influenced by evaluative biases or stereotypical judgments (Scherer, 2007). Relevant deficits include an inappropriate self-image, especially overly negative appraisals of one's coping potential, and over or under-estimation of the responsibility for the event by oneself or others. Habitually inaccurate or unrealistic appraisals are implicated in reduced well-being and a major risk for poor mental health (e.g., depression, anxiety) as evidenced by experimental and prospective studies examining cognitive style, attributional style, and cognitive biases (Alloy et al., 1999; Hertel & Mathews, 2011; Hong & Cheung, 2015; Huang, 2015). In educational or workplace contexts, appraisal biases related to dimensions of control, power, causation, and value reliably predict maladaptive emotions (e.g., test anxiety, boredom), general psychopathology, poor academic performance, and dropout from education (Pekrun, 2006; Pekrun et al., 2010).
- (2) **Adequate coping and regulation abilities**, especially the use of functional coping strategies, such as careful reappraisal of the event, choice of constructive responses, downregulating excessive arousal and controlling one's verbal and nonverbal

expressions and action impulses in line with social conventions. Lack of adaptive emotion regulation skills and preponderance of dysfunctional coping mechanisms are both related to risk for mental health problems (Aldao et al., 2010; Sheppes et al., 2015). One particularly dysfunctional strategy is **rumination**, defined as the tendency to repeatedly dwell on problems and feelings, which is an important process in the ECP model, reflecting recursive unhelpful appraisals. Of the adaptive and maladaptive emotional regulation strategies commonly examined, rumination typically has the strongest relationship with poor mental health (Aldao et al., 2010)

- (3) **Adequate emotion knowledge (awareness, recognition and understanding skills).** These skills include an understanding and awareness of the personal and situational factors that determine the elicitation of a specific emotion, accurate recognition and perception of one's own emotions and the emotions expressed by others, and empathic understanding and perspective taking for the emotional reactions of different people. Deficits include faulty understanding of emotion processes resulting in lack of empathy, the inability to communicate and share emotion with others, and a general lack of socio-emotional skills in interactions. Meta-analytic reviews find that emotion knowledge and understanding are positively related to social competencies and negatively related to both internalizing and externalizing problems in adolescents (Trentacosta & Fine, 2010; Castro et al., 2016) and adults (Sanchez-Alvarez et al., 2016; Marsh & Blair, 2008) and predict workplace performance for high emotional labour jobs (Joseph & Newman, 2010), and that emotion recognition ability is positively related to empathy, other-rated socio-emotional competence, relationship quality, cultural adjustment, and job performance (Elfenbein et al., 2007; Hall et al., 2009).

Moreover, there is evidence that training emotional understanding can successfully decrease internalizing and externalizing problems and improve social functioning, employability and well-being (Izard et al., 2011; Trentacosta & Schultz, 2015; Nelis et al., 2011). By solidly basing both assessment and intervention on the ECP model, ECoWeB has significant advantages over traditional approaches. First, it allows us to directly target hypothesized underlying mechanisms common across all individuals no matter their symptomatology, allowing us to examine comorbidity issues. It also makes it more appropriate for well-being promotion and prevention of poor mental health than approaches that have been typically derived from clinical disease models. Second, by focusing on emotional processes that can be assessed and trained through standardized tasks, it can be scaled-up in a digital format. Third, the operationalization of the different, theoretically derived EC facets provides scope for personalizing interventions based on each individual EC risk profile rather than a generic socio-emotional intervention.

All parts of ECoWeB will be related to the ECP model: identification of higher-risk groups will be based on the assessment of deficits in specific EC components from the model and self-



help components (i.e., psychoeducation, tips, advice) offered will directly target these EC components. Our long-term goal is to develop comprehensive assessment and self-help for all major facets of EC that link to reduced well-being and/or psychopathology. For feasibility within a 4-year period, ECoWeB will necessarily focus on a reduced set of variables, assessments, and self-help interventions to test proof-of-principle for this approach. We selected target processes that meet the following criteria: (i) implicated in the ECP model; (ii) represent all 3 ECP components (production, regulation, knowledge); (iii) robustly implicated in mental health and/or well-being based on prospective longitudinal and/or experimental data, (iv) measurable with validated and scalable tests, and (v) existing and readily adaptable interventions that can be made scalable at a population level. On this basis, the target processes selected are appraisal biases (for production component); rumination (for regulation component); emotional knowledge, understanding and recognition (for emotion knowledge component) (see WP3-5 for further details). The majority of our self-help elements will be derived from established interventions proven to be effective: the extension beyond the state-of-the-art will be (i) delivering via a scalable self-help app to young adults; (ii) personalising their selection against EC profiles, and (iii) evaluating in a large prospective cohort against usual practice and an established non-personalised control self-help. Likewise, our primary outcomes will be focused on establishing proof-of-principle that these approaches can be helpful in promoting well-being and preventing poor mental health – in the context of the 4 year project, self-reported distress (anxiety, depression), well-being, and social and workplace functioning will be the indices of beneficial outcomes.

**Personalization:** Personalization is the use of interventions tailored to the specific needs of the individual. Personalised interventions are proposed to be more acceptable, efficacious, and cost-effective than generic interventions, with some notable examples of success, e.g., vemurafenib for the treatment of metastatic melanoma; ivacaftor for the treatment of cystic fibrosis. However, this approach has not yet been applied or evaluated in wellbeing and mental health, despite recent arguments for predictive, personalised, preventive and participatory medicine that is focused on individual well-being (ESF Forward Look: Personalised medicine for the European Citizen, 2012). ECoWeB will break new ground in applying personalization principles to mental well-being. ECoWeB provides a unique opportunity to forward this agenda with respect to young adult's mental well-being, through developing means to assess and train EC on a large scale and taking the first steps to match interventions to EC profile.

**Digital Delivery of EC self-help:** The use of the internet and apps to provide psychological Behavioural Intervention Technologies (BITs; Schueller et al., 2013) is an emergent approach, with evidence that computerised treatments (Andrews et al., 2010) and BITs in particular have efficacy for anxiety (Carlbring et al., 2011) and depression (Mohr et al., 2010; Burns et al., 2011; Watts et al., 2013). ECoWeB adopts the BIT approach (Mohr et al., 2014), based around a app platform to deliver the EC-facing self-help, because it has multiple benefits that are



pertinent to the challenge of providing an effective scalable population-oriented prevention intervention to young adults:

- (i) Unlike traditional interventions where the delivery of the therapy session or dose of medication to an individual means that it is used up and cannot be delivered again, apps can be used repeatedly by a nearly unlimited number of people simultaneously (i.e., non-consumable). Hence, a successful BIT has potential to be a low-cost, highly scalable Massive Open Online Intervention (Munoz et al., 2015) accessible to nearly all young adults;
- (ii) BITs can be used at anytime, anywhere in the world, maximising convenience for the user, and can easily be adapted across languages;
- (iii) BITs are integrated into daily life and the real world through being always available and on hand via smartphones, and can track behaviour as it happens and be responsive to events as they happen through self-report, prompting alternative responses when needed, making them particularly well-suited for changing habits like rumination (Watkins & Nolen-Hoeksema, 2014).

Successful implementation of BITs requires that they are engaging, reinforcing, unobtrusive, secure, and of value to potential users, all necessary conditions to ensure sufficient uptake and use, without which the BIT can have little effect. For these reasons, ECoWeB will employ well-established principles to improve adherence and engagement with the developed BITs, such as making them aesthetically pleasing, including rewards, feedback, and some scope for customization, including animations, gamification of the digital EC self-help modules, automated tailoring, real-time engagement, logs of past app use, reminders to engage, and simple and intuitive interfaces (Bakker et al., 2016; Brown et al., 2016).

See section 3.1 for detailed hypotheses and research questions.

## **2.1 Assessment and management of risk**

This trial is categorised as: Type A = No higher than the risk of standard medical care

The psychological self-help to be used are generally considered to be safe. The EC interventions to be used will be based on providing psychoeducation, tips, advice, and simple strategies that builds on learning of everyday skills and is unlikely to be iatrogenic. Several elements of the EC self-help, including the targeting of rumination and attributional retraining have already been examined in a number of RCTs with no report of adverse events (e.g., Cristea et al., 2015; Hall et al., 2006; Perry et al., 2014; Topper et al., 2017) including in self-help formats. The focus of the self-help apps is on targeting general emotional competence skills (including appraisals of emotions, emotion regulation and emotional perception and understanding), i.e., it targets a non-medical condition, and is compatible with support of general emotional fitness and general well-being.

Other than the intervention failing to produce an effect, there is nothing in the literature to suggest possible adverse effects for the young adults involved. Versions of components within the EC self-help have been previously used with no detected harmful effect. As with all psychological approaches, 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 rumination intervention and indicated benefits over 12 months, with no serious adverse events reported: similar positive effects are found for attributional retraining and mind-set interventions, as such, these components of 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, participants receive more intensive monitoring, with processes to identify and direct all relevant participants to potential sources of help (e.g., youthinmind.info; Samaritans, General Practitioners; Teléfono de la Esperanza; contact list for child and adolescent psychotherapists in Germany provided by the German Federal Chamber of Psychotherapists; Bündnis Gegen Depression; FIDEO) including in response to reports of thoughts of suicide or self-harm.

Cautions seem particularly important for individuals with psychosis, mania, or current suicidal intention because they need more help than this intervention can provide. These psychiatric disorders will be an exclusion criterion in the study and the conditions will be carefully screened.

### **Cumulative efficacy information**

There is positive data from previous studies on the efficacy and feasibility of existing interventions that inform the current EC self-help components, including from face-to-face, digital and self-help variants. The attributional retraining intervention has been proven in RCTs to increase adaptive and reduce maladaptive causal attributions (Hall et al., 2006), improves long-term performance (course grades, Grade Point Average) and reduces drop out (effect sizes  $d = .43$  to  $.92$ ) in college and secondary school students including via short online video clips (mini-lectures on adaptive attribution enhanced by cartoon animation) suitable for app delivery (Perry et al., 2014). Similarly, the Mind-set intervention has evidence that it improves academic performance and Grade Point Averages in RCTs (Good et al., 2003; Paunesku et al., 2015; Yeager & Dweck, 2012; effect size,  $d = .52$  relative to control) including via computer-based delivery.

Meta-analyses of controlled trials of Cognitive bias modification of interpretation (CBM-I) suggest that CBM-I has a medium effect sizes (e.g.  $g = 0.81$ ) on changing interpretation biases and a small effect on changing symptoms of anxiety and depression in both adults and adolescents in face-to-face and web-based studies (Cristea et al., 2015, Hallion & Ruscio, 2011).

Ehring and Watkins have completed a Phase II RCT of guided internet self-help rumination training intervention versus group training versus usual care for Dutch young adults (n=251, aged 15-21) who were at high risk because of elevated worry and rumination (Topper et al., 2017). Retention was 87% at 12 month follow-up and internet guided self-help significantly reduced self-reported caseness of depression and anxiety relative to usual care (15% versus 32%). In this trial, the web-based training halved self-reported caseness of major depression and generalised anxiety disorder in at-risk young adults (15-22 years old) over 1 year (Topper et al., 2017; effect size relative to usual practice,  $d=0.89$  for reducing worry;  $d=0.55$  for reducing symptoms of depression). This provides proof-of-principle that an internet-delivered intervention can be beneficial for promoting resilience and reducing mental ill-health in young adults. In a further trial in the UK (ISRCTN12683436), we compared therapist-supported internet self-help versus usual practice in 235 undergraduates (18-25 years) at high risk because of elevated worry and rumination, and included an unguided self-help therapy condition to examine the feasibility of this approach (n=78, see protocol, Cook et al., 2016). This pilot suggested that an unguided self-help variant of this intervention is feasible, acceptable, and potentially efficacious for young adults. There was good adherence and acceptability for internet self-help: on average (mean) 46% of self-help modules were completed, equivalent to completion rates in therapist-supported version and consistent with wider literature; 27% of users completed all modules, 14% of users never logged on, at least on par with previous e-treatment studies.

We have pre-clinical pilot data indicating the short-term benefits of training emotional perception: training improved emotion recognition in young adults, with effects persisting over four weeks, and increased cooperative outcomes with strangers in a dyadic negotiation task and independent observer ratings of positive affect (Schlegel & Hall, in preparation).

A full risk plan can be found in the Appendix section 16.1

### 3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

#### ECOWEB PROJECT OBJECTIVES

ECoWeB is dedicated to cutting edge research on the mechanisms and determinants of mental well-being and poor mental health and proposes an innovative preventative and promotion approach to increase mental health and well-being in young adults. Specifically, we **aim to PROMOTE mental well-being and PREVENT poor mental health (and by extension in future the development of mental disorders) by developing, implementing, and testing an innovative population-oriented self-help app in young adults that assesses EC and then helps individuals in a personalised way based on an individual risk profile to enhance EC skills and rectify EC deficits via a self-help mobile health app.**

Specific objectives within the 48-month project are:

1. The development of a website platform and mobile app suitable to deliver both digital measurement and intervention tools in a flexible and integrated way and to deploy the solution in a scalable and effective way, working in close partnership with scientists specialized in user-centric design process and with commercial IT companies specialized in the health field **(WP2)**.

2. To successfully identify, adapt, and develop empirically validated assessment instruments for three major EC facets implicated in successful emotional, mental, and social functioning. This includes validating innovative digital assessment tools for these EC facets, starting with self-report and adaptations of our existing performance tests of EC ability, and moving to pilot novel measures fully utilizing mobile technology, e.g., automated analyses of voice parameters and ecological momentary assessment **(WP2-5)**.

3. The development of innovative, autonomous EC-related digital mobile app self-help that are highly scalable and open to all potential users. To make best use of the 4-year funding period, we will adapt existing interventions and look to better target them to individuals **(WP2-5)**.

4. The successful establishment of a large (N=2400+) longitudinal participant cohort consisting of adolescents and young adults across different European countries, including higher-risk groups, e.g., migrants and refugees, individuals with family histories of disorder, low social economic status (SES) or unemployment, low academic achievement and academic drop-out, difficult life circumstances and stressful events, and/or self-identified concerns with self-esteem, confidence, stress, worry, and rumination. This will enable us to test the prospective relationships between the different components of EC ability, and educational and occupational attainment, mental health, and mental well-being, and, thereby, to increase our knowledge and understanding of the underlying processes **(WP6)**.

5. The delivery of two cohort multiple randomized controlled trials (cmRCTs) to test proof-of-principle of the efficacy of the personalised EC intervention to respectively (a) PREVENT poor mental health as indexed by increasing anxiety and depression (i.e., general distress, non-specific stress) and reduced well-being and (b) PROMOTE mental well-being in young adults **(WP7)**, stratified on the basis of their EC profile (higher hypothesized risk/elevated EC deficits vs. normative range).

6. To assess the suitability of the personalised digital EC self-help in the pilot phase to access and engage young adults so as to improve their mental health outcomes, to determine the barriers and facilitators of successful implementation of the personalised EC self-help, and to clarify adaptations that might be needed to ensure the EC self-help can be used in specific vulnerable groups such as refugees and new migrant communities **(WP8)**.

7. Successful dissemination to include working with young adults to develop clear guidelines and recommendations with respect to the implementation of the self-help app to disseminate

the findings to relevant stakeholders, and the production of prototype digital EC assessment and self-help modules for wider roll-out (**WP9**).

A key overt aim of this project is to make the app of use and value to young adults and this goal has informed every step of the planned proposal. ECoWeB builds on extensive evidence and experience that has identified that these new technologies engage young adults and might access groups not previously accessing other forms of interventions. Beyond these specific objectives, we anticipate progress towards longer-term outcomes that go beyond the lifetime of this project including (a) the mobile app providing a delivery platform to which future interventions can be added; (b) continuous improvement of personalised prevention based on evaluation data; (c) moving from established measures used to identify risk in this project to innovative assessment instruments (piloted in the current project) making full use of digital technology to provide valid and scalable means to assess EC deficits indicative of high risk; (d) seeking further funding to extend the longitudinal cohort to assess longer-term effects.

### **ECOWEB Trial Objectives**

To evaluate the effectiveness of a personalised digital self-help app to enhance Emotional Competence (EC) skills as a universal (ECoWeB-PROMOTE) or targeted (ECoWeB-PREVENT) population-oriented public health approach to promote mental well-being and resilience among young adults (aged 16-22 years). The intervention has the potential to be scalable, easily available, low cost, convenient, acceptable, and to tackle equality of access (see also Kazdin, 2015).

More specifically, the objective is to compare the effect of usual practice including the use of an app to monitor emotions plus personalised digital EC self-help (personalised EC self-help) against usual practice (including self-monitoring on the app in the cohort study) plus a non-personalised digital automated self-help using generic cognitive behavioural (CBT) principles (online CBT self-help) and usual practice alone including self-monitoring (usual practice) over 3 month follow-up. Outcomes will be self-reported mental well-being (primary outcome) as well as resilience, depression, anxiety symptoms, social functioning, quality of life, and educational achievement (secondary outcomes).

## **3.1 Primary/secondary objectives and research hypotheses**

### **ECoWeB- PROMOTE Trial**

The primary objective in the ECoWeB- PROMOTE trial will be to evaluate mental well-being at 3-month follow-up (*primary endpoint*) in young people with an EC profile **without** elevated hypothesized risk, i.e. EC profile within the normative range, comparing participants receiving personalised EC self-help with those receiving a non-personalised digital self-help based on generic CBT principles and those receiving usual practice (plus app-based self-monitoring).

Mental well-being is the appropriate primary outcome for this general population as it will indicate whether EC training produces improvements in confidence, mood, and other positive aspects of mental well-being, consistent with the remit of this research programme.

The *primary outcome measure* for PROMOTE will be the 14-item **Warwick-Edinburgh Mental Well Being Scale (WEMWBS)**; Tennant et al., 2007), the leading validated self-reported index of wellbeing with excellent psychometric properties. It has been translated and adapted into numerous languages including the languages of the recruiting Centres of this clinical trial (English, French, Spanish, Dutch) (see Table 1). The primary endpoint will be the between group difference (i.e., comparing each intervention against each other and against usual practice) for the WEMWBS score at 3 months, with adjustment for baseline WEMWBS.

## Hypotheses

(1) young people with low risk on an EC profile, *personalised EC self-help* will outperform *digital CBT self-help* in

- increasing mental well-being at 3 months (1a; primary outcome; WEMWBS);
- increasing social and occupational/academic functioning (WSAS), quality of life (EQ5DL), at 3 months (1b) (secondary outcomes)
- reducing symptoms of depression (PHQ-9) and anxiety (GAD-7) at 3 months (secondary outcomes as general indices of poor mental health) (1c);

(2) young people with low risk on an EC profile *personalised EC self-help* will outperform *usual practice and self-monitoring* in

- increasing mental well-being at 3 months (2a; primary outcome; WEMWBS);
- increasing social and occupational/academic functioning (WSAS), quality of life (EQ5DL), at 3 months (2b) (secondary outcomes)
- reducing symptoms of depression (PHQ-9) and anxiety (GAD-7) at 3 months (2c; secondary outcomes as general indices of poor mental health);

(3) young people with low risk on an EC profile *CBT self-help* will outperform *usual practice and self-monitoring* in

- increasing mental well-being at 3 months (3a; primary outcome; WEMWBS);
- increasing social and occupational/academic functioning (WSAS), quality of life (EQ5DL), at 3 months (3b) (secondary outcomes)
- reducing symptoms of depression (PHQ-9) and anxiety (GAD-7) at 3 months (3c; secondary outcomes as general indices of poor mental health)

**Secondary objectives** will be: (1) to assess the effects of the intervention on primary and secondary outcomes over long-term (12-months follow up) and (2) at all time points (1, 3 and 12 months). The same hypothetical structure as above will be used.

## 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.

## ECoWeB- PREVENT Trial

The primary objective in the ECoWeB-PREVENT trial will be to evaluate poor mental health as indexed by symptoms of depression at the 3month follow up (*primary endpoint*) in young adults who are potentially vulnerable for poor mental health because of identified deficits in EC functioning (ECoWeB-PREVENT). The depression symptoms (amongst other outcomes including anxiety and well-being) of those receiving personalised EC self-help will be compared with those receiving non-personalised automated digital CBT self-help and those receiving usual practice (plus Self-monitoring app). Elevated symptoms of depression is a particularly meaningful endpoint in this population, as it is the most common and disabling of the mental health difficulties experienced in young adults, showing the greatest increase in incidence during this age period (Kessler et al., 2005). It also has the greatest impact in terms of disability and burden (Avenevoli et al., 2015), and, is chosen as our primary outcome as the best index of general poor mental health. Change in depressive symptoms also provides an excellent prodromal measure of potential long-term impact on onset of major depressive disorders: elevated symptoms are established as a robust predictor of higher risk for future episodes of depression (Rushton et al., 2002). Therefore, with respect to the remit of this call, and in light of the time-line for the project, change in depressive symptoms provides a good initial measure for proof-of-principle of the interventions to have a preventative effect in the longer-term.

The *primary outcome measure* for ECoWeB-PREVENT will be the state depression score of the participants on the **Patient Health Questionnaire-9 (PHQ-9)** (Kroenke et al., 2001). The PHQ-9 is a commonly used measure of depression. It assesses the recent state of depression (i.e. how the individuals feels over the last two weeks) using items that measure subjective feelings of low mood, loss of pleasure, fatigue, change in sleep and appetite, concentration, suicidality, corresponding to diagnostic criteria for a major depressive episode. The PHQ-9 has been translated and adapted into numerous languages including the languages of the recruiting Centres of this clinical trial (English, French, Spanish, Dutch) (see Table 1). The primary endpoint will be the between group difference (i.e., comparing each intervention against each other and against usual practice) for PHQ-9 at 3 months, with adjustment for baseline PHQ9.



## **. Hypotheses**

(1) Young people with high risk on an EC profile *personalised EC self-help* will outperform *digital CBT self-help* in

- reducing symptoms of depression at 3 months (1a; primary outcome, as index of poor mental health; PHQ-9);
- reducing symptoms of anxiety at 3 months (1b); (secondary outcome, as index of poor mental health; GAD-7)
- increasing mental well-being (WEMWBS), social and occupational/academic functioning (WSAS), quality of life (EQ5DL) at 3 months (1c). (secondary outcome).

(2) Young people with high risk on an EC profile *personalised EC self-help* will outperform *usual practice and self-monitoring* in

- reducing symptoms of depression at 3 months (2a; primary outcome, as index of poor mental health; PHQ-9);
- reducing symptoms of anxiety at 3 months (2b) (secondary outcome, as index of poor mental health; GAD-7);
- increasing mental well-being (WEMWBS), social, occupational/academic functioning (WSAS), quality of life (EQ5DL) at 3 months (2c) (secondary outcome).

(3) Young people with high risk on an EC profile the *digital CBT self-help* will outperform *usual practice and self-monitoring* in

- reducing symptoms of depression at 3 months (3a; primary outcome; as index of poor mental health; PHQ-9);
- reducing symptoms of anxiety at 3 months (3b; as index of poor mental health; GAD-7);
- increasing mental well-being (WEMWBS), social and occupational/academic functioning (WSAS), quality of life (EQ5DL) at 3 months (3c).

**Secondary objectives** will be: (1) to assess the effects of the intervention on primary and secondary outcomes over long-term (12-months follow up) and (2) at all time points (1, 3 and 12 months) The same hypothetical structure as above will be used.

Additional secondary outcome measures will assess anxiety, mental well-being, social functioning, quality of life, and educational achievement (see Table 15).



### 3.3 Outcome measures

Table 13: WP6/7 Outcome measures for ECoWeB –PROMOTE, ECoWeB- PREVENT – all are used in both trials

Measure	Description	Reliability and Validity
<b>PRIMARY OUTCOMES</b>		
<b>Warwick-Edinburgh Mental Well Being Scale (WEMWBS;</b> Tennant et al., 2007; Stewart-Brown et al., 2009) <u>Primary Outcome Measure for ECoWeB PROMOTE; Secondary outcome for ECoWeB- PREVENT</u>	14-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. Available in English, Spanish, German, and Dutch versions.	Leading measure of well-being. 14-item version validated from age 16 upwards; Cronbach's $\alpha$ =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).
<b>Patient Health Questionnaire-9 (PHQ-9;</b> Kroenke et al., 2001) <u>Primary Outcome Measure for ECoWeB PREVENT; secondary outcome measure for ECoWeB-PROMOTE</u>	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. Available in English, Spanish, German, and Dutch versions.	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 $\alpha$ =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 $\geq 10$ , 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).

Measure	Description	Reliability and Validity
<b>SECONDARY OUTCOMES</b>		
<b>Generalized Anxiety Disorder-7 (GAD-7;</b> 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. Available in English, Spanish, German, and Dutch versions.	Leading measure of anxiety widely used in clinical trials, clinical practice, and as part of the UK NHS IAPT MDS. Cronbach's $\alpha$ =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.
<b>Work and Social Adjustment Scale (WSAS;</b> 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 $\alpha$ 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.
<b>Quality of Life (EuroQol 5D-3L;</b> Herdman et al., 2011)	The EQ-5D-3L is a three-level and five-dimension questionnaire covering quality of life in the domains of mobility, self-care, usual activities, pain/discomfort and anxiety/ depression. Each dimension consists of 1 questionnaire with 3 response options EQ-5D is a standardised measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal, including for the estimate of Quality Adjusted Life Years (QALYs) (Feng et al., 2016) and health equality/inequality. The utility scores of the EQ-5D can be used to calculate the quality adjusted life year (QALY) during the follow-up period by adjusting the length of time affected through the health outcome by the utility value.	EQ-5D-3L has been validated in a diverse patient population in 6 countries, including 8 patient groups with chronic conditions (cardiovascular disease, respiratory disease, depression, diabetes, liver disease, personality disorders, arthritis, stroke) and a student cohort.
<b>Adult Service Use Schedule (ADSUS-adapted)</b>	The ADSUS is a well-established measure within the health economics field used to index relevant health and social care costs for trial participants. It has been used for adults and adapted for adolescents, and developed in previous trials. It asks a series of readily adaptable questions (for context) about how many times the participant has seen various	The AD-SUS has been used to support health economic analyses in a number of large-scale clinical trials (e.g., PREVENT, COBRA) (e.g., Kuyken et al., 2015; Green et al., 2011). Versions of the AD-SUS have been developed in a number of clinical trials (Byford et al., 1999; 2006; 2007).

Measure	Description	Reliability and Validity
	health professionals (e.g., GP or nurse at surgery or at home; psychiatrist, therapist), had overnight stays in hospital or hospital appointments or attendances, medication use and use of social services. This measure is used to estimate the direct healthcare and social care costs of individuals who do or don't receive an intervention.	
<b>BACKGROUND AND DEMOGRAPHIC MEASURES</b>		
<b>Demographics</b>	Date of birth, gender, country in which live	
<b>Educational achievement</b>	Educational achievement will be assessed in three standard and well-established ways: (a) a hierarchical classification of the highest level of completed education as self-reported by the participant using six categories based on the International Standard Classification of Education (ISCED) 1997 (elementary/primary level; lower secondary, upper secondary; post-secondary non-tertiary; first stage of tertiary education; secondary stage of tertiary education); (b) years of completed full-time education to date; (c) self-reported grades of the main subjects (mathematics, native language, first foreign language) [where applicable].	These are standard means for assessing educational attainment, and as recommended by the guidelines Report on Monitoring socio-economic inequalities in health in the European Union, prepared by the Health Monitoring Program of the European Commission.

Measure	Description	Reliability and Validity
<b>LIDAS (Lifetime Depression Assessment Self-Report Questionnaire)</b>	<p>The Lifetime Depression Assessment Self-report questionnaire (LIDAS), Bot et al, 2017) assesses lifetime major depression (MDD) diagnosis according to DSM criteria, and is largely based on the widely used Composite International Diagnostic Interview (CIDI). It has been proven to be effective for determining history of depression through self-report in an online digital format, matching the needs for the current study.</p> <p>LIDAS is a promising tool for rapid determination of lifetime MDD status in large samples, such as needed for genomics studies. In the current study, it was used to more accurately determine past and current diagnostic status for depression at baseline and at 3 month and 12month follow-ups. It consists of a conditional sequence of pre-programmed questions assessing all the diagnostic criteria for depression, with logic cut-outs so that subsequent questions are determined by prior questions – as such participants can answer between 3-30 questions. Available in English, Spanish, German, and Dutch versions</p>	<p>Sensitivity and specificity were adequate. User-friendliness of the instrument was rated high. Median completion time was 6.2 min. Sensitivity and specificity for lifetime MDD were 85% [95% confidence interval (CI) 80–91%] and 80% (95% CI 72–89%), respectively, against a reference of the standard CIDI diagnostic interview. The instrument gave a prevalence of lifetime MDD in line with reported population prevalence, (Bot et al., 2017).</p>
<b>AEQ Adverse Events Questionnaire</b>	<p>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 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 moderator of any treatment effects. We adapted the questionnaires to include</p>	<p>Carver (1998) found that this measure predicted subsequent depressive symptoms six weeks later in undergraduates and interacted with cognitive vulnerability factors to predict depression, as did Beevers and Carver (2003) in a subsequent study,</p>

Measure	Description	Reliability and Validity
	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.	
<b>Occupational status</b>	The participant is asked to provide information on current occupation, which is then used to classify the participant into an occupational class, using standardized international class schemes based on the EGP (Erikson, Goldthorpe and Portocarero) scheme and using a standard approximation to this scheme, the International Socio-Economic Index of Occupational Status (ISEI) developed by Ganzeboom et al. (1992, 1996). Because this is a young sample aged 16-22 and a number will not yet be in the workforce, we will also assess parental (mother and father) occupational status in order to estimate socio-economic status for each individual.	This socio-economic status scale has a range from 10 to 90. At the bottom are unskilled manual jobs in which wages and levels of education are low and at the top are the professionals, proprietors, and managers. A distinction is made between upper and lower non-manual classes, skilled and unskilled manual classes, farmers and other self-employed. This is a well-established and frequently used means to classify occupations and estimate socio-economic status, that has high reliability and validity and is recommended by the guidelines report on monitoring socio-economic inequalities in health in the European Union, prepared by the Health Monitoring Program of the European Commission. It allows us to assess occupational status mobility by examining whether occupational status has increased, decreased or stayed the same over the assessment time points.
COVID-19 (supplementary question)	Since the COVID-19 pandemic began UK charities and mental health organisations have been reporting poorer mental health in young people. This may change over the course of the trial and possibly between recruitment and follow up when restrictions are lifted. The following questions aim to capture whether at the time of assessment lockdowns are in place, and the impact of those lockdowns on ppt mental health.	New measures: Are your current movements restricted by any lock down due to Coronavirus Not at all (1).....(7) completely restricted To what extent is the coronavirus pandemic affecting your mental health now? Not at all (1).....(7) very much affected

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## Health Economics Measures

Several measures in the cohort will enable us to make quantitative estimates of economic and social benefits and of change in inequality, including (a) educational attainment; (b) change in occupational status, (c) a self-report scale of functional impairment in work and social settings (see Table 1), (d) a well-established measure of quality-of-life (EQ-5D-3L). We will test whether the personalised digital EC self-help enhances these outcomes relative to online CBT self-help and usual care (including self-monitoring) controls, and whether the interventions benefit those specifically disadvantaged on these outcomes at baseline (i.e., those with social or health inequalities, e.g., migrants, low SES).

Health and social care utilisation will be collected using an adapted version of the Adult Service Use Schedule (AD-SUS). Developed for mental health trials, the AD-SUS questionnaire quantifies the use of healthcare resources, use of medication and employment and time off work over the trial including follow up (Richards et al., 2016, Kuyken et al, 2015, Byford et al., 1999; Barrett et al., 2006). Adaptation will include time away from school or college together with changes to the wording to ensure relevance across the four countries. The AD-SUS will be administered at baseline to assess use of services in previous 3-months, at 3-month follow-up, ask about use of services since the baseline interview, and 12-month follow-up, ask about use of services since the 3-month interview.

The adapted AD-SUS will enable a preliminary estimate of per person costs in each country using recommended methodology for economic evaluation (Drummond et al, 2015).

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

### Additional measures: Emotional Competencies – potential mediators of clinical outcomes

We will assess the EC abilities using the instruments developed in WP3-5 at baseline, 1 months, 3 months and 12 months, enabling us to examine whether the interventions differentially change EC skills and whether this mediates change in symptoms.

**Table 14: EC Outcome measures for ECoWeB –PROMOTE and ECoWeB PREVENT Trials**

Measure	Description	Reliability and Validity
<b>WP3a</b>		
EMODIS	The EmoDis tool represents an innovative approach to measure emotion dispositions and underlying appraisal biases, a central constitutive part of the EcoWeB agenda. For this project, a short form was developed. Participants are asked to imagine experiencing 4 standard scenarios and rate their appraisal on 5 dimensions and the intensity of experiencing one or more of 5 emotions. Following validation studies this is shortened further to rating of 3 appraisal dimensions and intensity of 3 emotions across 4 standard scenarios. (already shortened from 6 to 4 scenarios and from 14 to 10 ratings)	The original scale was developed in two stages A) measuring emotion dispositions in HR assessment sessions with N>3000 professionals from several countries, B) measuring the relationship between appraisal bias and emotion dispositions in a representative US panel study (N=200). The instrument showed satisfactory reliability and excellent discriminate and convergent validity (e.g., low control/power appraisal bias accounting for over 30% of the worry responses). It also correlates consistently with personality and various background factors. (Scherer, submitted). These findings were largely confirmed in the Gent sample. The EmoDis is one of the few instruments in EcoWeB to measure dispositions and risk rather than symptoms.
Control belief scale	5 item short form of a personality scale developed in collaboration with the Swiss Household Panel (SHP) to measure beliefs about one's control, power, and personal efficacy. It is expected to identify a stable disposition to over- or underestimate one's control/power/coping ability with adverse events. Following validation studies, it was shortened to 4 items. Available in English, Spanish, German, and Dutch versions	The original scale was validated in the SHP (N>4000) showing good reliability. It accounts for a sizable proportion of the variance in both emotion disposition and the frequency of depressive experiences (Scherer et al., submitted) The short form tested in the Gent sample also showed satisfactory reliability and the expected correlations with appraisal bias and emotion disposition.

Measure	Description	Reliability and Validity
	(already shortened from 12 to 5 items)	
<b>WP3b</b>		
Achievement Appraisal Scales	Achievement Appraisals are assessed with short versions of (1) Perceived Academic Control (PAC) scale (Perry et al., 2001), (2) Dweck's (2006) Growth Mindset Scale; (3) Wigfield's (1994) Academic Value Scales, The value scales assess intrinsic value, utility value, and achievement value (importance of success, importance of failure). On the basis of the results of the analysis of the validation studies the number of items has been reduced from 21 to 14.	Leading measures of appraisals related to achievement. Each of them validated in > 100 studies, including cross-cultural studies. High internal consistencies, clear factor structures, substantial relations with achievement-related emotions, behaviour, and educational attainment.
Achievement Emotions Questionnaire (AEQ)	The ECoWeb Achievement Emotions Questionnaire (AEQ) is a 21-item self-report instrument that contains short versions of the enjoyment, anxiety, hopelessness, and boredom scales of the original AEQ (Pekrun et al., 2011). The AEQ measures lack of positive emotion and excessive negative emotions in the achievement domain (i.e., achievement emotions disorders; Pekrun et al., in press). There are three versions for achievement contexts at high school, university, and work. Items are answered on a 1-5 Likert scale (1 = <i>strongly disagree</i> , 5 = <i>strongly agree</i> ). On the basis of the results of the analysis of the validation studies the number of items has been reduced from 21 to 12.	Leading measure widely used in research on achievement emotions, applied evaluation research (e.g., international programmes of student assessment) and student counselling. Cronbach's $\alpha$ s ranged from 0.82 to 0.92, one-year retest reliabilities from 0.61 to 0.66. Validated in high school and university students in > 100 studies. Internal validity is documented through reliable factor structures. Correlations with academic achievement are $r \geq 0.30$ .
<b>WP3c</b>		
ASRQ = Social rejection questionnaire	Rejection Sensitivity Questionnaire (ARSQ; Berenson et al., 2009). Rejection sensitivity (RS) is a cognitive-affective processing disposition to anxiously expect rejection, shaped by cognitive social learning history and triggered in situations when either rejection or acceptance is possible. The RS-Adult questionnaire (A-RSQ) is an adaptation of the RSQ (Downey & Feldman, 1996) for assessing RS in adult research participants. It consists of 9 scenarios describing social situations/requests (e.g., You call a friend when there is something on your mind	Strong psychometric properties and may potentially be an equally good measure of negative appraisal biases in young people. Internal consistency (alpha) = .89 (for each administration) Test-retest reliability (Spearman-Brown coefficient) = .91 Scores were significantly higher in the borderline personality disorder group (M =14.86, SD=6.09) than in the healthy comparison group (M = 6.19, SD = 2.80), $t(63.4) = 8.58$ , $p < .001$ .



Measure	Description	Reliability and Validity
	that you feel you really need to talk about), each of which is rated for level of concern or anxiety that the relevant person would not respond positively ("rejection concern"), rated on a 1 to 6 scale from 1 "very concerned" to 6 "very unconcerned", and for expectation that the other person would accept the request and respond positively ("acceptance expectancy"), rated on a 1 to 6 scale from 1 "very unlikely" to 6 "very likely". This "acceptance expectancy" is reverse scored, i.e., 7-acceptance expectancy to provide an index of rejection expectancy. Overall rejection sensitivity is calculated by multiplying rejection expectancy by rejection concern. On the basis of the results of the analysis of the validation studies the number of scenarios has been reduced from 9 to 8.	Berenson, Downey, Rafaelli, Coifman & Paquin (2011). The rejection-rage contingency in borderline personality disorder. <i>Journal of Abnormal Psychology</i> , 120, 681-690.
<b>WP4</b>		
<b>Ruminative Response Scale- Brooding (RRS-B;</b> (Nolen-hoeksema & Morrow, 1991) <u>Assess risk, personalisation, predictor, secondary Outcome</u>	The brooding subscale of the RRS (Nolen-hoeksema & Morrow, 1991) is used as a "depression-independent" scale which measures dysfunctional rumination. The scale consists of 5 items which can be rated from '1' (never) to '4' (always), resulting in a total score from 5 to 20. Versions available in English, German, Dutch, Spanish	Higher levels of brooding predict depression (Treyner et al., 2003; Moberly & Watkins, 2008). Internal consistency for the brooding subscale is Cronbach's alpha = .75 (Schoofs et al., 2010). In the Ghent sample: RRS-B: .72 (5 items, N=737 associated with more depression in longitudinal analyses (Treyner, Gonzalez & Nolen-Hoeksema, 2003) Correlated with depressive symptoms concurrently ( $r = 0.54$ , $p < 0.01$ ) and six months later ( $r = 0.49$ , $p < 0.01$ ) (Samtani & Moulds, 2017)
Penn State Worry Questionnaire ( <b>PSWQ-A;</b> Hopko et al., 2003) <u>Assess risk, personalisation, predictor, secondary Outcome</u>	The PSWQ-A (Hopko et al., 2003) is an abbreviated 8-item version of the original 16-item questionnaire that aims to measure the trait of worry, using Likert rating from 1 (not at all typical of me) to 5 (very typical of me). Research suggests that the instrument has a strong ability to differentiate patients with generalized anxiety disorder (GAD) from other anxiety disorders. Available in English, Spanish, German, and Dutch versions.	Cronbach's alpha = .89 for the PSWQ-A (Kertz et al., 2014), in the Ghent sample: PSWQ-A: .92 (8 items, N=738) e.g., predicted future symptoms of anxiety and depression. (Topper et al., 2014) "Rumination and worry are partly responsible for the cross-sectional and prospective co-occurrence of

Measure	Description	Reliability and Validity
		affective disorders and may be suitable targets for treatment” (Drost et al., 2015).
<b>WP5</b>		
<b>CEUT</b>	The CEUT-S is a shortened form of the CEUT – The Components of Emotion Understanding Test which was developed on the basis of the Componential Emotion Approach. Participants read a series of emotion eliciting situations each containing emotional reactions that align with emotion components. The participant rates the likelihood of each emotional reaction in the situation on a 5-point response scale (Very unlikely, Unlikely, Neither likely/Nor unlikely, Likely, Very likely). The original form (also called SASTEU) has 10 situations in which participant rates 30 questions per situation (300 items). The shortened form contains 7 emotion eliciting situations and 6 emotional reactions (42 items). For ECoWeB purpose, this was further reduced to 6 scenarios with 4 questions each (24 items)	The only measure that assesses understanding of all five emotion components of the Componential Emotion Approach (appraisals, action tendencies, bodily reactions, expression, subjective feelings). Test has been validated with Black and White students in South Africa. The test has a good reliability (Cronbach’s alpha of .89). The test correlated with verbal ability, self-report emotional intelligence, emotionality, extraversion, conscientiousness, openness to experience, positive affect, and self-esteem, and was negatively correlated with somatic complaints (Sekwena & Fontaine, 2017).
Geneva Emotion Recognition Test Short (GERT-S) GERTS-20	GERT-S is a 42-item performance-based emotion recognition test in which participants view short video clips of actors expressing 14 different emotions. After each clip, participants choose which of 14 emotions had been expressed by the actor. For Ecoweb, a very brief version of this original brief test with 20 items was created Schlegel, K., & Scherer, K. R. (2016). Introducing a short version of the Geneva Emotion Recognition Test (GERT-S): Psychometric properties and construct validation. Behavior Research Methods, 48(4), 1383–1392. The GERT was originally developed from the Geneva Multimodal Emotion Portrayals (GEMEP) corpus (Bänziger et al., 2012), which contains 1,260 audio-video clips (duration 1–4 s) of 18 emotions portrayed by 10 actors with different intensities	The GERT-S reached Cronbach’s alphas of about .80 in several samples in different languages. It is a Rasch-homogeneous and unidimensional test. It correlates as expected with other measures of emotional intelligence, personality, alexithymia, intelligence etc. (see Schlegel, Fontaine, & Scherer, 2017; Schlegel & Scherer, 2016). For the very brief 20 item version, the items with the best item discrimination parameters were chosen based on data from various studies. Reliability of this version is unknown.

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### **3.4 Primary endpoint/outcome**

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

All participants will have had the opportunity to use the App for 3 months at their own discretion so at that point the trial is powered to see if the personalised Emotional Competence self-help is superior to the CBT self-help (active control) and to the usual care self-monitoring control in promoting well-being (ECoWeB-PROMOTE trial) or preventing poor mental health (ECoWeB-PREVENT trial). The 3month primary endpoint was chosen:

- a. to maximise power and sensitivity to intervention as closer to actual use of intervention
- b. to reduce the negative impact of drop-out attrition on study power
- c. to increase comparability to other studies using mental health apps as this is a typical end-point in app interventions
- d. to provides a proof-of-principle of changes in known predictors/analogues of poor mental health such as depression and anxiety – i.e., if we can show change in depression symptoms, rumination or other EC measures at 3 months, then we are likely to predict the future impact of the intervention on the onset of future emotional disorders. This can be checked at the 12month follow up (i.e., this is consistent with a prevention-mechanism trial – Zalta & Shankman 2016). Prevention Mechanism trials are deemed successful if an intervention reduces well-established risk factors for development or maintenance of psychopathology or increases established resilience factors. Such trials may help identify novel interventions that target multiple known risk factors, and in turn, strategies most likely to reduce dysfunction.
- e) there is an expectation of relatively high attrition by the 12month follow-up due to competing demands on the attention and motivation of young adults. The Youth Advisory Board advised that staying in the trial for 3 months would be reasonable, but they might lose interest over a longer period. The highest number of participants returning follow ups is likely to be at 3 months.

### **3.5 Secondary endpoints**

The secondary endpoint is the 12 month follow up for all trials, which is included to test if any effects found at the primary endpoint are maintained over time. Because any change in the symptoms of poor mental health may take time to manifest, the 12month follow-up will also be used as a secondary outcome to test if there is medium-term effect of the active interventions on improving well-being and reducing poor mental health (depression, anxiety), relative to the control arms.

### **3.6 Exploratory endpoints**

There are no exploratory endpoints.

### 3.7 Endpoints/outcomes

**Table 16 Endpoints/outcomes**

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

Work Pckge	Measure	Detail	Size	Base line	4 weeks	3 months	12 months
6/7	Pre-screening (pre consent)	Language Country under which participating, Gender, ethnicity, confirmation of likely eligibility re current mental health	1 item 5 items	X  x			
6/7	Age Screening	Date of birth	1 item	x			
6/7	WEMWBS	Primary outcome measure (ECoWeb-PROMOTE); secondary outcome (ECoWeb-PREVENT)	14-item	X	X	X	X
6/7	LIDAS current and past inclusion exclusion criteria items	Screening for past depression	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, Last 3 months, and ever		X, last 3 months	X, last 12 months
6/7	PHQ9	Primary outcome (ECoWeb-PREVENT), secondary outcome (ECoWeb-PROMOTE)	9-item plus 3 conditional risk questions	X	X	X	X

			parental past health 2 items				
<b>End of screening and start of EC/risk of measures</b>							
6/7	GAD7	Secondary outcome measure	7-item	X	X	X	X
WP4	RRS Brooding	Used for EC. Used for risk and personalisation algorithm	5 items	x	x	x	x
WP3b	Rejection sensitivity questionnaire	Used for EC Used for risk and personalisation algorithm	16 items	x	x	x	x
6/7	WSAS	General Functioning	5-item	X	X	X	X
WP4	PSWQA short form	Used for EC Used for risk and personalisation algorithm	9 items	x	x	x	x
WP5	GERT (Geneva Emotion Recognition Task)	Used for EC Used for risk and personalisation algorithm	20 videos	x	x	x	x
WP5	CEUT-short form	Used for EC Used for risk and personalisation algorithm	6 items with 4 options	x	x	x	x
6/7	Demographics	Self-educational level,	2 questions in 6 parts	X	Status only	status only	status only
WP3b	Achievement Appraisal	Used for EC Used for risk and personalisation algorithm	14 items in 3 versions	x	x	x	x

WP3b	Achievement Emotion Questionnaire	Used for EC Used for risk and personalisation algorithm	12 items in 3 versions	x	x	x	x
6/7	EQ5-D3L	Quality of Life	6-item	X		X	X
WP6	ADSUS-adapted Physical health demographic	Estimate of health costs	2-14 items  1 item	X (excluding anxiety and depressive items)		X 3mth	X 12mth
End of screening/tailoring measures and start of additional measures							
WP 3a	EMO control scale Dis belief	Control	4 items				
WP3a	Emotion reaction tendencies		4 scenarios with 6 ratings each, 24 questions	x	x	x	x
6/7	Further demographics		employment gender/country at birth parental occupation/employment Country of birth, gender at birth, sexuality,	x			
WP6	AEQ	Adverse events/stressful life events	5 item			x	x

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## 4 TRIAL DESIGN

### Design

We will undertake Phase III superiority parallel 3-arm randomised multicentre, multinational cohort multiple randomized controlled trials (cmRCTs). Our study design follows MRC Complex Interventions Guidelines and the theoretical mechanisms targeted by intervention have been confirmed. The design of the trials is illustrated in Figure 1 (page 21).

The trial design is one of two cohort multiple randomized controlled trials (cmRCT; Relton et al., 2010) all within the ECoWeB longitudinal cohort, in which eligible individuals within the prospective cohort meeting relevant criteria are selected at random to be offered self-help components within a mobile phone app or to not be contacted about the offered self-help within the app. All participants in the cohort consent at the outset to provide data to be used to look at the benefit of the app self-help for the outcomes of interest (see Figure 2). The cmRCT approach combines the benefits of a prospective longitudinal cohort with a randomized trial: random selection of some is equivalent to random allocation of all with respect to distributing known or unknown prognostic factors evenly at baseline and enabling strong inference about causal effects of the intervention, whilst retaining key comparison groups that provide information as to the natural history of the condition across individual differences (including high-risk and low-risk groups without self-help).

**Conditions.** Appropriate participants (see inclusion/exclusion criteria in 1.4) will be randomly allocated on 1:1:1 to the following three conditions using an intention-to-treat (ITT) approach:

- (A) Offered a personalised digital self-help EC app plus usual practice continuing within the cohort (*experimental intervention group*)
- (B) Offered a non-personalised automated digital CBT self-help app plus usual practice continuing within the cohort (*active control group*)
- (C) Usual practice alone, continuing within the cohort without being offered any self-help and using an app configured only for self-monitoring (*usual practice control group*)

**Assessment points.** Within the prospective cohort, the same outcome measures will be obtained at baseline (M0), at 1 months (M1), 3 months (M3) and 12 months (M12).

## 5 TRIAL SETTING

The recruitment centres are the University of Exeter, UK, leading on recruitment from the UK; LMU leading on recruitment from Germany; UGent leading on recruitment from Belgium; and UJI leading on recruitment from Spain. These recruitment centres were chosen because they each have expertise in large-scale recruitment and clinical trials, provide a diversity of European experience and cover four of the major European languages. This is therefore a multi-centre trial with all 4 sites being involved in both trials with the same processes across the main cohort. Participants from all 4 countries will be directed to the trial recruitment website where (in each of the 4 languages) they can find out more information about the study. Those interested will then link to Qualtrics where they will be screened, give informed consent and complete the baseline assessment. The interventions will be provided through different configurations of the App which are hosted by MONSENSO, who are a grant holder. Follow up data will be collected online through Qualtrics and then collected by, stored and organised by the EXCTU database. Researchers at each site will promote participation in the study, answer enquiries and chase follow ups. The intervention is therefore not provided at the site. Participants are not patients or those with any current psychiatric condition.

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## 6 PARTICIPANT ELIGIBILITY CRITERIA

### ECoWeB-PROMOTE Trial

The sample will be a selected group of 16 to 22-year olds from within the larger cohort longitudinal study (WP6), who do not indicate potential increased vulnerability for poor mental health at the baseline assessment (M0). This assessment is completed on the screening website. The EC profile is based on the assessed battery of EC skills (**production**: functional pattern of appraisal biases [WP3]; **regulation**: functional patterns of coping and regulation, and lower scores of rumination/worry [WP4], **emotion knowledge**: functional emotional understanding and perception [WP5]). Thresholds will be finalised during the validation studies in WP3-5, but we estimate that thresholds will be set so that approx. 66-75% of participants will be eligible for the ECoWeB-PROMOTE study (i.e., those scoring below the risk thresholds; risk thresholds will be based on worst performing quartile/tertile on each measure, based on prior studies finding this to predict increased risk, e.g. Topper et al., 2017 and on recent evidence that this is an appropriate cut-off, Hankin et al., 2018).).

We will exclude those individuals reporting current or past history of depression on screening measures. Those with current episodes of psychiatric disorders (e.g., major depression) or any bipolar disorder, 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.

### ECoWeB- PREVENT Trial

The sample will be a selected group of 16 to 22 year olds from within the larger cohort longitudinal study (WP6), who indicate potential increased vulnerability for mental illness at the baseline assessment (M0) completed on the online/app test battery in the form of more extreme scores on the EC components. Our screening criteria for being a vulnerable young person will be showing significant and/or multiple deficits on the EC profile based on the assessed battery of EC skills (**production**: dysfunctional pattern of appraisal biases [WP3]; **regulation**: dysfunctional patterns of coping and regulation, especially high scores of rumination/worry [WP4], **emotion knowledge**: deficits in emotional understanding and perception [WP5]). Thresholds will be finalised during the validation studies in WP3-5, but we estimate that thresholds will be set so that approx. 25-33% of participants will be eligible for the ECoWeB-PREVENT study (i.e., those scoring above risk thresholds; risk thresholds will be based on worst performing quartile/tertile on each measure, based on prior studies finding this to predict increased risk, e.g. Topper et al., 2017).

We will exclude those individuals reporting current or past history of depression on screening measures. Those with current episodes of psychiatric disorders (e.g., major depression) or any 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.

## 6.1 Inclusion criteria

### ECoWeB-PROMOTE Trial

#### Inclusion criteria

- (1) Aged 16-22, in the UK, Spain, Belgium and Germany.
- (2) **not** indicating elevated vulnerability based on the EC profile within the baseline assessment (as described above);
- (3) basic literacy in English, Spanish, German, or Dutch, as indicated by ability to complete consent and online questionnaires (12year old reading age or better).



- 
- (4) Ability to provide informed consent
  - (5) Available for the full duration of the study (12 months)
  - (6) Regular access to a relevant smart phone (using android or IOS systems)

## **ECoweB-PREVENT Trial**

### **Inclusion criteria**

- (1) Aged 16-22, in the UK, Spain, Belgium and Germany
- (2) screened for elevated vulnerability criteria on their Emotional Competence profile as assessed within the baseline assessment (as described above);
- (3) basic literacy in English, Spanish, German, or Dutch as indicated by ability to complete consent and online questionnaires (12year old reading age or better).
- (4) Ability to provide informed consent
- (5) Available for the full duration of the study (12 months)
- (6) Regular access to a relevant smart phone (using android or IOS systems)

## **6.2 Exclusion criteria**

### **ECoweB-PROMOTE Trial**

#### **Exclusion criteria**

- (1) Meeting criteria on self-report electronic screening questionnaires for any of the following
  - a. current episode or past episode of major depressive disorder reported on the LIDAS and PHQ9
  - b. any diagnosis of depression
  - c. active suicidality; or
  - d. any history of severe mental health problem (i.e., bipolar/psychosis);
- (2) Currently receiving psychological therapy or counselling or antidepressants or other psychiatric medication.
- (3) Elevated vulnerability on their emotional competence as assessed within the baseline assessment

### **ECoweB-PREVENT trial**

#### **Exclusion criteria**

- (1) Meeting criteria on self-report electronic screening questionnaires for any of the following
  - a. current episode or past episode of major depressive disorder reported on the LIDAS and PHQ9
  - b. any diagnosis of depression
  - c. active suicidality; or
  - d. any history of severe mental health problem (i.e., bipolar/psychosis);
- (2) Currently receiving psychological therapy or counselling or antidepressants or other psychiatric medication.

## **7 TRIAL PROCEDURES**

Young people meeting inclusion criteria will be enrolled in the cohort via the study website. Once enrolled and consented, each participant will be followed for a minimum of 12 months, with assessments at each of

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1, 3 and 12 months. UNEXE will have overall responsibility for the monitoring of the delivery of the recruitment and retention into the cohort across all participating countries.

All baseline assessments will be online through the trial website which leads through to a series of questionnaires created with Qualtrics. The trial website will host a welcome screen with informational videos and a choice of language from English, German, Dutch and Spanish. The website will link to the privacy and data protection policy for the trial in the relevant language and this will be downloadable.

A Qualtrics site programmed by the Exeter team will then host:

- Pre-screening collection of basic demographic information (country,) so that we have information on who was excluded and why. There will be a series of pre-screening questions asking about previous mental health which are linked to help pages in the relevant countries. Those confirming mental well-being and the absence of a history of depression then click forward to the age screen. Full details of the questions asked and information provided in the help pages can be found in Appendix 16 of this protocol.
- Following pre-screening there will then be a date of birth check to see if the participant is eligible for the trial and if they need parental permission to consent to take part in the trial (if they are from Germany or Belgium). Those needing parental permission will be asked to complete their parents contact details and an email will automatically be sent to their parents with information about the trial and a unique link for them to give parental permission for their child. After parental consent has been given, the participant is automatically sent an email link to return to the consent page. If aged under 16 or over 22 then the recruit will automatically link to a page explaining they are outside of the age range for the trial. Participants will not be able to click back to re-enter a different date of birth.
- In the consent (a) questionnaire the information sheet will be presented in selected language and consent form with fields for completion. Consent A asks for consent to take part in the 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. The recruit will automatically be emailed a copy of the information sheet, the privacy policy and the consent form for their records.
- In the baseline assessment, potential recruits will be presented with a series of questionnaires designed to see if the trial is right for them/they meet eligibility criteria. Those excluded will be automatically routed to pages detailing why, with links to sources of help. There will be pages tailored for current/past depression, suicide risk, mania/psychosis and these (downloadable) pages will be in the language for the appropriate country. It is hoped that having been provided with the option to self-screen out with depression in the pre-screening phase of assessment that very few people will screen out for depressions or risk during assessment.
- Those meeting eligibility criteria will be asked to complete a series of questionnaires designed to assess their emotional competence so they are funnelled into the appropriate trial. The trial they enter will be based on cut-offs on the emotional competence assessment measures (see 6 above).
- Participants will be asked to complete further questionnaires to learn more about their current mental and emotional wellbeing, behaviours, views and environment so that the research teams can learn more about what predicts wellbeing, poor mental health and the response to the different self-help versions of the app.
- Participants will be asked demographic questions regarding their gender, ethnicity, occupation, parent's occupation and schooling.
- At the end of the baseline assessment, non-excluded participants will be asked to consent to take part in the trial.
- 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

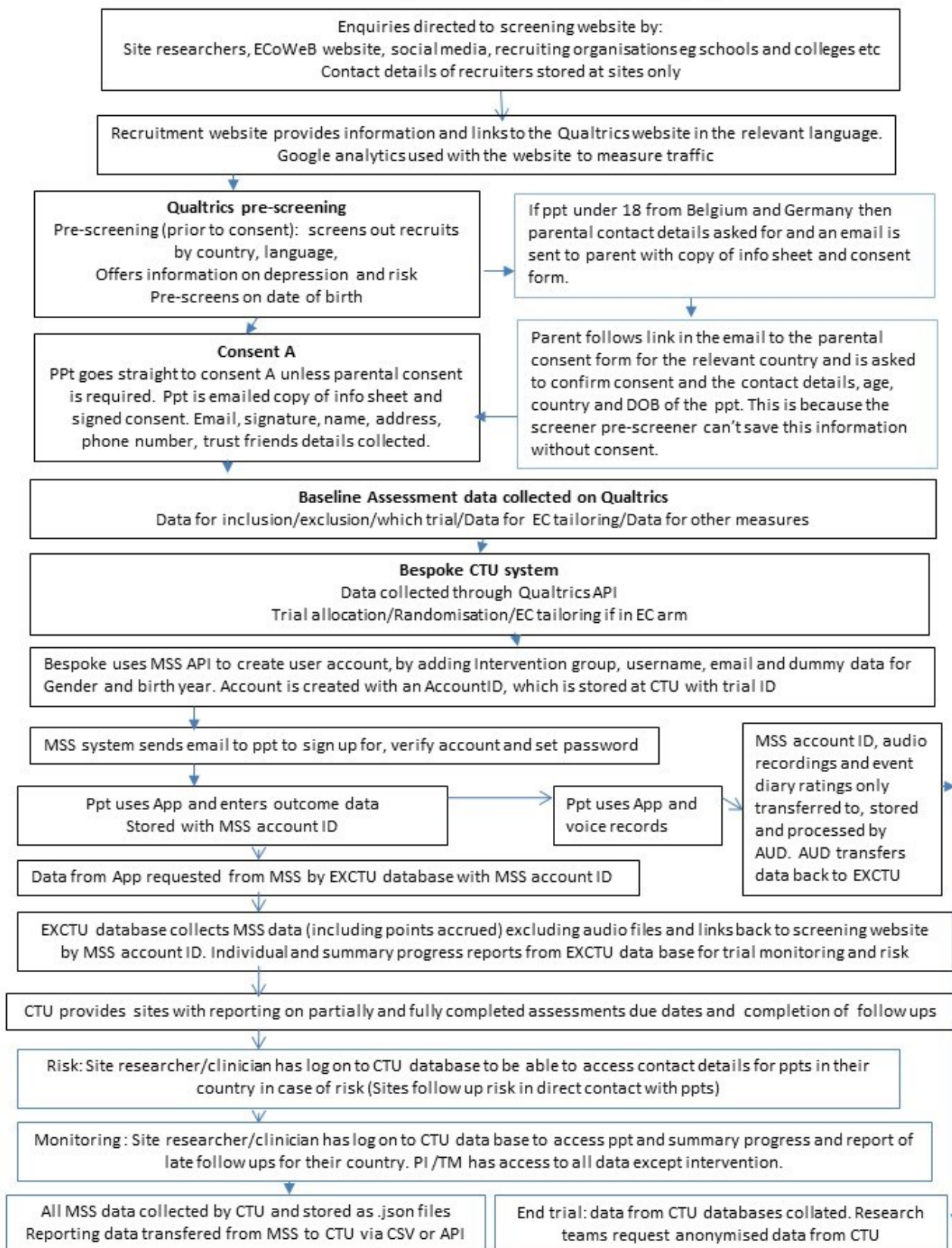
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questionnaires ask about well-being in the last 2 weeks so if the time period was longer, those results would be out of date.

- When the participant has completed their assessment, a trigger is sent to the CTU database which signals it to collect all the participant's data through the Qualtrics API.
- When participants consent to take part in the trial participants will be allocated (using the trial allocation algorithm) in to one of the 2 cmRCT trials (as detailed in the inclusion and exclusion criteria) and randomised into one of the 3 conditions: usual practice plus personalized digital emotional competence (EC) self-help (the novel experimental intervention), usual practice plus digital CBT self-help (active control) and usual practice including self-monitoring (the usual practice control condition).
- Consenting participants will automatically be signed up to use the app via an API. MSS will be sent their email address, the language and which condition they are randomised to. The MSS account number will be collected and stored with the trial number on the EXCTU website so these accounts can always be linked.
- The MONSENSO data management system will then email the participant a link so that they can set a password and download the app.
- Participants will complete their version of the self-help app completing general mood and emotion monitoring and, where provided, receiving tips, strategies and advice for promotion and prevention through self-reflective and learning exercises, watching animations, reading texts, listening to sound clips, answering quizzes and tests. There is no measurement of risk or symptoms on the app but there will be a help menu available at all times with helpful information for their country and the contact details of the site researcher. The app does not provide diagnosis, features intended to calculate clinical risk or clinical decisions, or features intended to influence an actual treatment. There is no communication with a therapist.
- If participants choose to use the audio recording feature on the app then acoustic features extracted from the voice files on the smart phone and their masked and de-identified (randomly -spliced) voice files will be encrypted and sent securely to collaborators AUD.
- The survey site programmed in Qualtrics 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 1, 3, and 12. The data will automatically be collected through the API and stored on the EXCTU database.
- The only data collections at sites would be by the site researcher on the telephone if the participant has not completed their follow up and is willing to complete the primary outcome measures only on the phone.

A flow diagram of how the data flow will work between EXCTU, MSS and AUD can be found on the following page:

**ECoWeB data flow diagram Protocol version 1.1 dated 05/09/2019**



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## 7.1 Recruitment

### Recruitment strategy

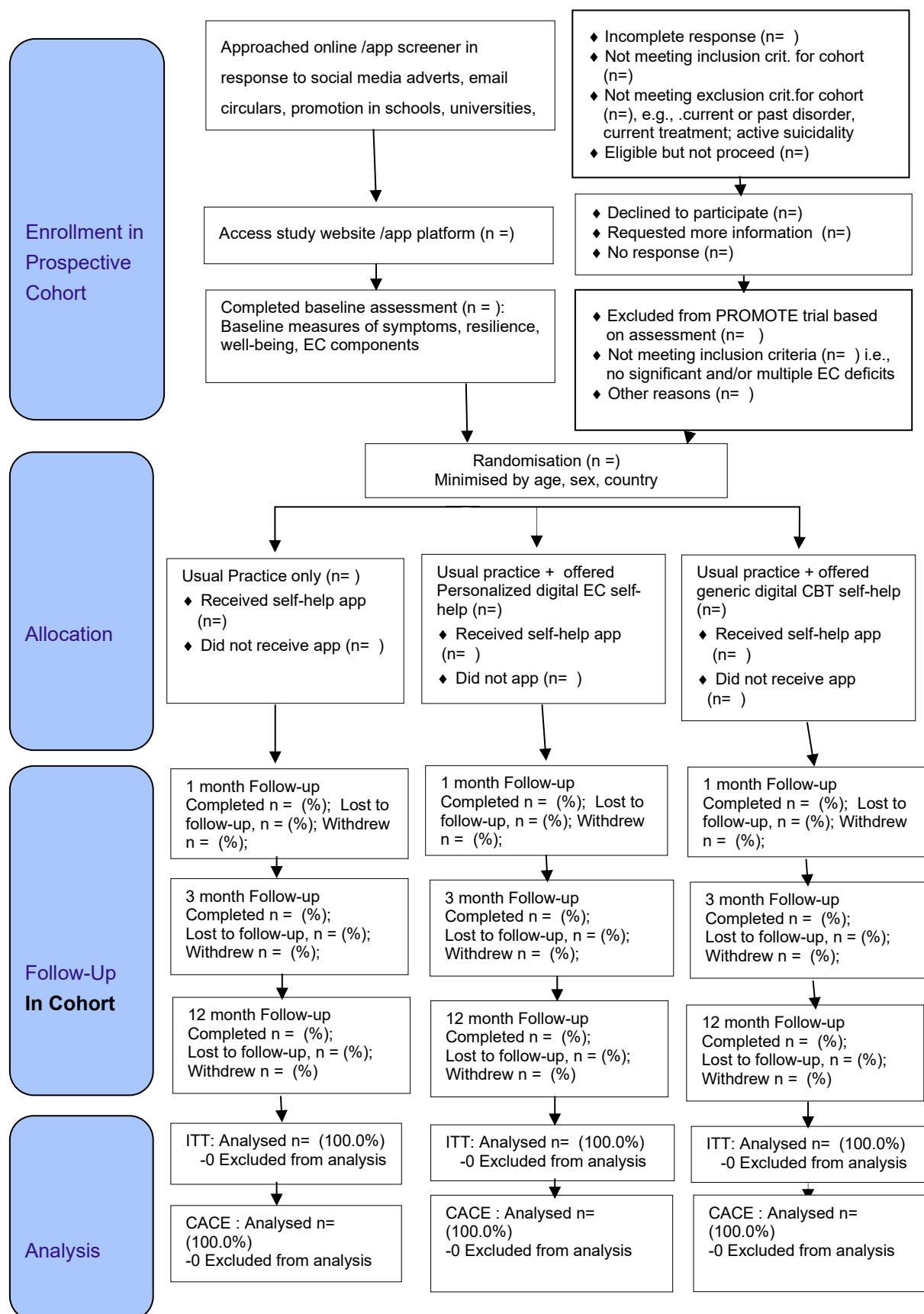
#### Pilot study

A testing phase will be run to confirm the feasibility of recruiting participants in the age range 16-22 to the cohort, to assess trial methods to optimise recruitment and retention for the trial, and to maximise the acceptability, efficiency, robustness, and appropriateness of data collection and management methods, in order to optimise the main trial phase. In particular, we will beta-test all the electronic and automated systems within WP6 and WP7, including screening and consent process, collection and capture of online data from the website/app platform, randomisation process and delivery of relevant applications. This will be focused on checking all trial systems work properly and fully debugging them before the main cohort recruitment proper begins. This will be coupled with examination of the participant experience of the delivery of the EC assessment website and app platform (in conjunction with WP8) in order to optimise recruitment, retention, acceptability, and adherence.

In addition, there will be an internal pilot for the first four months of the study: the results of the pilot study will be contribute to the main trial but provide a focused opportunity to monitor recruitment, retention and intervention uptake, and to enhance procedures and process without changing key methodological elements of the trial (i.e., interventions, eligibility criteria, design, randomisation, outcomes will remain unchanged), but procedures around recruitment and assessment could be adapted.

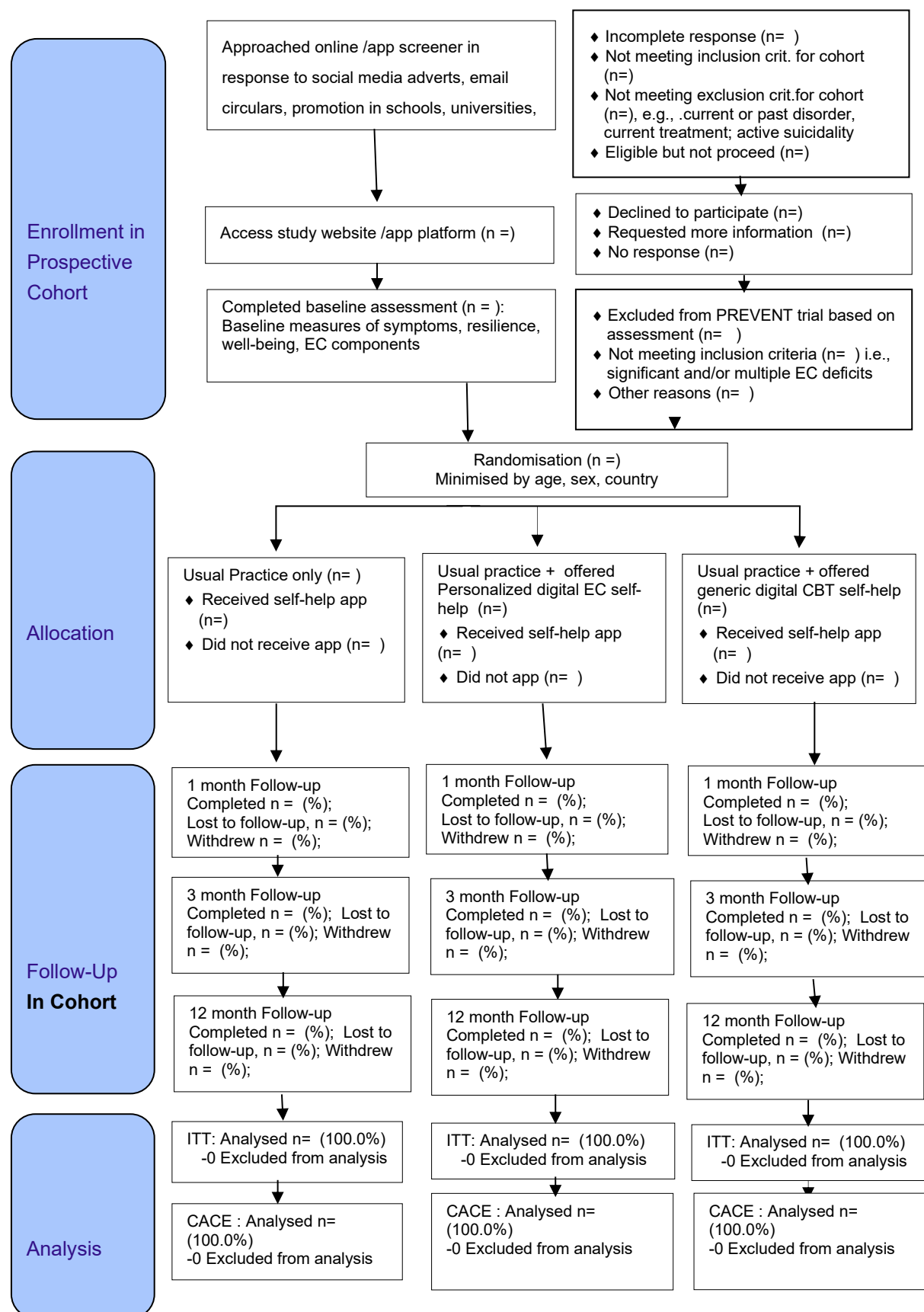
The consort diagrams for the full trials can be found on the following pages:

**Figure 2: Consort Flow Diagram for ECoWeB PROMOTE 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.





**Figure 4: Consort Flow Diagram for ECoWeB PREVENT 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 population and, in addition, specifically target first and second-generation migrants and refugees, individuals with family histories of disorder, low SES, low academic achievement and academic drop-out, difficult life circumstances, stressful events, and/or self-identified concerns with self-esteem, confidence, stress, worry, and rumination to oversample a higher-risk group. All participants in the cohort consent at the outset to provide data to be used to look at the effect of the self-help versions of the app for the outcomes of interest. 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. We emphasize that we are recruiting from the general population and that this project is focused on a population-level intervention approach, focused on general emotional regulation skills and well-being. It does not recruit a clinical population.

Recruitment of the cohort will follow successful models (e.g., <http://www.mappiness.org.uk/>, 66,000 participating), with study and app advertised as a means to find out about, monitor, and potentially enhance one's own emotional functioning as well as competencies to succeed in one's career and successfully interact with others. Using proven methods, and as recommended by the UK Young adult's Mental Health Advisory Group (YPMHAG) and the University of Exeter's emergent Young Adults' Lived Experience Group (YPLEG), site researchers will recruit participants through

- multiple traditional and social media (posting and advertising on Facebook, YouTube, Instagram, SnapChat, Google, MySpace, Twitter, 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, colleges/secondary schools, youth services, local social health clinics, youth clubs, the German site will apply at the Ministry of Education to recruit in schools;
- snowballing approaches;
- random selection of residents via the city council (in Germany);
- Approaching adult patients that have children in the age group (from earlier study cohorts, clinics, professional mental health services)
- promotion to at risk groups, targeted adverts (e.g. by geographical area), health portals, and via relevant charities over 12 months across the recruitment sites (UK, Germany, Spain, Belgium; e.g., UK Children and Young adult's Mental Health Coalition (CYPMHC, <http://www.cypmhc.org.uk/>) YoungMinds; StudentMinds; FIDEO, fighting depression online; [www.itgetsbrighter.de](http://www.itgetsbrighter.de), <http://www.kids-und-co.de>; Bündnis gegen Depression, Teléfono de la Esperanza; Fundación Adsis).

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), whereas in Germany 97% of 12-19 year olds have an internet connection at home and more than 93% have a smartphone (IZI, 2017). Similarly, in Spain the use of the Internet is a majority practice in young adults aged 16 to 24 years, with 98.6% in men and 98.2% in women (INE, 2017). Research generally shows familiarity with and positive approach toward digital media in adolescents (Oh et al., 2008).

The ECoWeB project has already activated accounts in several social media to provide information about the project. These accounts will be used to aid recruitment in the trial:

- YouTube: <https://www.youtube.com/channel/UCRhE9DyIUZqSPcn00COVe9Q>
- Twitter: @ECoWeB\_Project [https://twitter.com/ECoWeB\\_Project](https://twitter.com/ECoWeB_Project)



- Facebook: <https://www.facebook.com/proyectoECoWeB>
- Instagram: [https://www.instagram.com/ECoWeB\\_project](https://www.instagram.com/ECoWeB_project)
- Vimeo: <https://vimeo.com/user80647181>
- LinkedIn: <https://www.linkedin.com/in/ECoWeB-project-849525159/>
- Google+: <https://plus.google.com/u/3/116532953230982313706>

No patients 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 cohort study and screening for suitability in a logical conditional sequence (e.g., self-reported age, language, current and past history of mental disorders). Individuals who met these eligibility criteria proceed to more detailed information and provide consent to join the cohort. All members of the cohort will have access to the ECoWeB App but what version they get will depend on the condition that they are randomised to. The baseline assessment is automatically provided through the study website. 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 app.

### **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 2,400 participants recruited into the cohort over 12 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 Germany, LMU has an official agreement with the district administration council (Kreisverwaltungsreferat, KVR) to invite by post a random selection of people living in Munich meeting pre-defined demographic criteria to participate in research studies: based on prior studies finding participation of 5-10% of those contacted via the KVR and c. 45,000 young adults aged 16-20 living in Munich, LMU anticipates meeting our recruitment targets. This was a successful recruitment strategy in previous studies. The UJI site in Spain has extensive successful experience of recruiting to EU-funded online treatment projects (e.g. OPTIMI, I-CARE; Botella et al., 2016; Mira et al., 2017). We have experience at successfully recruiting from schools (representative sample of 3500+ adolescents with participation rates >90% in German PALMA longitudinal study, Pekrun et al., 2007; collaborations with the Centra voor LeerlingenBegeleiding pupil support service linked into all Flanders schools for Belgium site UGent).

### **7.1.2 Screening**

Participants will be screened by a purpose-built website programmed within Qualtrics by University of Exeter and those under 16 and over 22 will automatically be screened out pre-assessment. Those aged 16/17 who live outside of the UK and Spain will require parental permission to take part in the trial and will automatically be taken to a separate page on the screen. On this page they will be asked to complete their parent's contact details and the parent will be sent a link to give parental permission on Qualtrics. After parental permission has been collected, an email will be sent to the participant providing them with a link to return to the survey at the point of consent A. 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. For those with current depression that are not indicating risk we will provide information on where to get help for symptoms of depression and advise that they contact their GP.

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### 7.1.3 Payment

Participants will be paid in electronic shopping vouchers or equivalent for taking part in the three follow up assessments; we will pay 10 euros/pounds for completing each of the 3 follow ups. Participants will also be able to gain badges that they can exchange for rewards through the gamification system of the App. The gamification system on the app will reward the earning of badges at different levels (complete all available badges at bronze earn 10 euros/pounds, complete all at silver earn 10 pounds/euros; complete all at gold earn 10 pounds/euros). The maximum honorarium a participant can gain for using the App is 30 euros/pounds, so the participant can earn up to a maximum of 60 pounds for taking part in the study. European participants will be paid in Euros.

MSS will transfer information on the number of badges earned to the EXCTU system where it can be linked with the completion of follow ups and the appropriate amount paid in vouchers. Researchers will be able to run reports on the EXCTU database to identify which participants have earned badges and completed follow ups at the key payment points (after 3month and 12month follow ups). Site researchers will arrange for the payment of participant using electronic shopping vouchers (or equivalent) which can be emailed or sent by text. An automated system of voucher will be created (if possible). 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 distinguish between 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 (age of majority is aged 16 or over for the UK and Spain and 18 or over for Germany and Belgium) versus those adolescents and young adults who are below the age of majority in their respective country, and for whom both their own informed assent and permission from their parents or legal guardian (dependent on nation and jurisdiction) is necessary for their participation.

See section 7.1.2 for more information on the parental permission process.

Participants aged 16/17 from Belgium and Germany will not be able to take part until a signed parental permission form has been received by the site.

Obtaining informed consent for those above the respective age of majority for the country of recruitment will be a two-stage process. For those who need parental permission there will be a pre-consent process to obtain parental permission first. Then there will be the same process described below of providing consent to undertake the assessment and then providing consent to take part in the study is followed.

Young people will be initially routed to or seek out the study website and after age screening 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 screening website. 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. The recruit will then be asked to complete 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.

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If a participant completes the baseline assessment and is eligible for the cohort and trial then they will be presented with consent form B 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. Our Youth Advisory Board advised us that most recruits would probably want to continue and gain access to their App at this stage and would be discouraged by having to wait. There is therefore an option for the participants to consent to take part in the cohort/trial at the end of the assessment. On completion of consent form B participants are advised that our App developer MSS will be emailing them a link to access their App and when their next follow up is due. At this stage the recruit is randomised and be given a unique participant trial number.

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

Our proposed procedures for recruiting and screening young people into the cohort have previously been approved by local and national ethics committees, and we will obtain approval before commencing the study. In all centres, each PI who is recruiting participants for the prospective cohort will ensure that the necessary arrangements for agreement to access and use of data are respected by researchers and site training will be provided by the trial manager. The sponsor will take out civil liability insurance to protect participants.

### **7.2.1 Additional consent provisions for collection and use of participant voice recordings**

The option to voice record a diary record will be possible in the emotion diary part of the App. This function will be available in all versions of the app and all trial conditions. This option is described in the information sheet and the privacy and data protection policy. The participant is also explicitly asked to confirm that they know there is the option to voice record. Participant would have to press record for this function to become active.

## **7.3 The randomisation scheme**

Random selection to the 3 arms (offering EC self-help app; offering CBT self-help app; or continuing with self-monitoring app alone – usual practice) will be conducted automatically by means of a secure web 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 minimize allocation by sex, country from which participant is entering the trial (reflecting trial site; i.e., UK; Spain, Germany, Belgium), and age (16-17 vs. 18-22 years). We split the sample into two age ranges to reflect naturally occurring transitions (e.g., between secondary education vs. tertiary education; into the workforce) and that the concerns and issues of 16/17 year olds may differ from those of 18 to 22-year olds. To maintain concealment, the minimisation algorithm will retain a stochastic element and the first 50 participants will be allocated to each by simple random allocation.

### **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 before any analysis is

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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 custom-built web service which interfaces with the EXCTU database. This will be an automated process. The EXCTU database will send MSS the email address and the version of the App that the participant is randomised to. The participant will automatically be set up with an MSS account and this account number will be recorded and linked to the trial number. Once the MSS account has been set up, the participant will receive an automated email from MSS providing instructions on how to access their version of the App. In the unlikely case that it is necessary, site researchers will be able to log on to the EXCTU website to identify which condition the participant has been allocated so that they can give advice on any problems the participant has in using the App. If this happens then this will be logged as an unblinding. The functioning of the randomisation programme will be checked by the data team and reported to the DMEC.

Detailed procedure for randomisation

1. Participants are allocated to one of 2 trials within the cohort:
  - a. ECoWeB-PROMOTE (EC profile indicates low risk for emotional difficulties),
  - b. ECoWeB-PREVENT (EC profile indicates higher risk for emotional difficulties)

For each trial, participants are randomised on a 1:1:1 basis into the 3 arms on an intention-to-treat basis: usual practice plus offered personalized digital EC self-help (the experimental intervention), usual practice plus offered digital CBT self-help (active control) and continuing with usual practice including self-monitoring app (control). Gender, age and country are used for minimisation.
2. The system must record the allocation and the date randomised.
3. The participant and researcher remain blind to the allocation.
4. If the participant is randomised to the EC condition (in any of the trials) then the EC profile from step 5 will be used to tell Monsenso which version of the App to provide the participant with.
5. An algorithm (simple set of rules) will be provided to determine the version of the app received within the personalised EC configuration and the bespoke website will communicate this information to Monsenso. This will be based on trial, interventions and EC category.
6. The system notifies Monsenso of the allocation. They will need to be notified of the version of the app, trial no, participant language and participant email address.
7. On successful randomisation, a finish page is displayed with a message telling the participant to look for an email message from Monsenso.

## **7.4 Blinding**

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

Site researchers will be blind to treatment allocation but will be in direct contact with participants to follow up risk and to answer technical queries. It is possible that a site researcher could become unblinded

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during those (infrequent) conversations if the participant mentions details of their version of the App. Participants will need to have someone who speaks their language to ask about technical queries as lack of technical support has been found in other studies to increase attrition. The App host MSS cannot provide this support because their staff do not speak all 4 languages.

Should a site 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 at the site (if available). Therefore, only blinded site researchers will attempt to collect the primary outcome measures by telephone if the participant is unwilling to use the screening website for this purpose. Unblinded site researchers will not discuss information relating to condition with blinded site researchers. During any contact with participants the blinded site researcher will remind them not to divulge to which version of the App they were allocated. In the event that there are no unblinded researcher at a site 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 site researcher 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 TSC (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 clinical 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 app 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 TSC/DMEC.

The TSC/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) in order 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 1, 3, and 12-months post randomisation. The 3-month follow up will be the primary endpoint. All assessments will be through the survey website programmed in Qualtrics. Only if participants have not responded to email and text prompts to complete their follow ups at 3 or 12-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



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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 Appendix 16.

## **7.8 Long term follow-up assessments**

Participants will be followed up at 12 months following randomisation. The structure and nature of this follow up will be the same as the 3 month follow up. There will not be any follow up after 12 months.

### **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 estimate a likely loss-to-follow-up at 3 months of 30% (70% retention), but have powered for a 40% loss-to-follow-up to build further redundancy into the study, given the uncertainty of ongoing app usage. This possible attrition has been factored into our calculation of power and sample size.

In order to maximise retention, we plan to update participants and other key stakeholders about the study's progress through social media and the ECoWeB 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 app/website and by sending regular updates and news, including upgrades and new content in the app, and by obtaining (with participant permission), relevant electronic contacts (e-mail; mobile telephone), repeated automated attempts to contact, use of app and text reminders for completing follow-up assessments, and an honorarium for each completed assessment. In addition, gamification and animation will be used to make the interventions appealing to our target group. 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 App, 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. We will withdraw participants from the trial on parental request if they are unable to legally consent for themselves (e.g. participants from Belgium and Germany who are aged under 18 at the date of the request). 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.

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## 7.12 End of trial

The final follow ups are due in September 2021 and the project will end on 31<sup>st</sup> December 2021. Any early termination of the trial will be reported to the ethics committee within 15 days.

## 8 TRIAL ARMS

### **Personalised digital EC self-help (experimental intervention group)**

The experimental arm is Emotional competence (EC) self-help incorporating Smartphone application (app) delivery. This EC self-help programme draws on the Emotional Competence Process model, which is based on an empirically validated theoretical process model of emotion (Scherer, 2007).

The ECP model distinguishes three EC component processes: (a) appropriate emotion production requiring an accurate appraisal of emotion-eliciting events including their causes and one's control over them; (b) adequate emotional regulation processes, with deficits including dysfunctional processes such as rumination; (c) adequate emotion knowledge (perception and understanding skills). The personalised digital EC self-help provides psychoeducation, tips, advice, exercises and training for each individual on the 2 EC components deemed to be most appropriate based on the baseline assessment. Thus, the intervention involves providing users access to specific modules within a suite of relevant EC psychoeducation and strategies, each of which is based on established socio-emotional learning principles and for which there is empirical evidence of beneficial effects.

The personalised digital EC self-help will be delivered via smartphone app 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 app will include text, pictures, audio-recordings, animations, audio-exercises to practice, questionnaires with tailored feedback and quizzes, and gamification (e.g., levels, rewards, feedback). The app will be designed for iOS and Android use. The content will focus on providing psychoeducation, tips, advice, strategies and reflective exercises and learning tests relevant to emotional regulation and understanding to aid promotion of well-being and prevention of poor mental health.

The use of a smartphone app is especially pertinent to the proposed theory of change, as it facilitates further practice in daily life, can prompt and remind users to practice, and keeps adaptive strategies always on hand via the mobile phone, thereby, potentially improving engagement and adherence. The app is accessed through a secure password protected log-in on a Smart phone. As autonomous self-help, no one delivers the intervention. It is completed by young adults at a pace, schedule and location they find convenient, any time of night or day, through their personal Smartphone, including on the go. There is no limit on the volume of individuals who can use it. As a secure, password accessed, self-help app, it offers increased privacy and anonymity. The app design ensures the intervention is administered as designed and retains fidelity to treatment model. It is a low cost means to increase access for disenfranchised and minority populations, those in isolated geographical areas and outside the educational system.

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All versions of the EC personalized self-help app will include the default self-monitoring features (including a regular daily mood rating and an event diary) which will be the usual practice self-monitoring control. This is monitoring of general emotions and replaces the use of a written diary or log of moods.

Each of the EC training components will build on existing and validated interventions and/or develop from experimental tasks shown to be beneficial in the laboratory.

There will be two self-help components or training EC production focused on different dimensions of appraisal biases:

(a) An *achievement-focused control value self-help component* will target appraisal biases related to maladaptive emotions linked to dimensions of power and causation (internal/external attribution of causes). This self-help builds on the control-value theory of achievement emotions (Pekrun, 2006), and includes: (i) attributional retraining (targeting perceived control), a video-based short intervention that has already proved successful with college students (Perry et al., 2014); (ii) mindset training (targeting perceived control and promoting growth mind-sets; Paunesku et al., 2015); (iii) utility value self-help (targeting perceived value of achievement), which has been shown to be effective with minority students (Hulleman & Harackiewicz, 2009). Elements focused on building perceived control and a growth mindset, have been shown to reduce and prevent depression and anxiety in young people even after a single 30-min session over 9 months (Miu & Yeager, 2015; Schleider & Weiss, 2016).

(b) A *social-focused self-help component* will target the systematic negative appraisals of social situations, that is, when individuals tend to make negative appraisals of ambiguous social situations (e.g., perception of rejection, criticism, exclusion). The training will build on well-established Cognitive Bias Modification-Interpretation training approaches, which have been shown to be effective at changing biases and facilitating more adaptive emotional responses in the laboratory (Cristea et al., 2015; Hallion & Ruscio, 2011; Mathews & Mackintosh, 2000), and for which there is emergent preliminary evidence of being beneficial for reducing depression and anxiety in individuals with elevated symptoms (Cristea et al., 2015; Hallion & Ruscio, 2011). The training will involve repeated exposure to ambiguous social scenarios with participants forced to adopt adaptive non-rejecting interpretations in the context of an ecologically-relevant stressor (CBM-I). Previous interventions have used text or audio-recordings to provide scenarios, and resolution is based on completing word fragments.

There will be a self-help component for improving EC regulation, targeting the shift away from maladaptive rumination and worry to more adaptive problem-solving. This module of the self-help builds on evidence-based developments that focus on identifying warning signs and repeated practice to train people out of unhelpful habits (rumination, self-criticism) and build helpful habits for resilience (problem-solving, self-compassion) (Watkins, 2008; Watkins et al., 2008, 2009, 2011, 2012). The intervention utilises well-established and proven cognitive-behavioural therapy principles and builds on existing effective guided web-based interventions (Topper et al., 2017). The app self-help coaches and advises participants to spot warning signs for rumination, worry, and stress and to repeatedly rehearse and practice an alternative strategy to such signs, using implementation intentions (If-Then plans) e.g., being more concrete, opposite action, problem-solving, relaxation, self-compassion, assertiveness. This innovative training approach is well-suited to unguided self-help as it involves easy-to-follow simple rehearsal of skills linked into daily life: it is a stepwise departure rather than a proxy to therapy. In addition, focusing on habit change may produce prolonged and amplified benefit beyond 1 year (Watkins et al., 2011). The combination of a focus on easily identifiable non-stigmatising, and motivating risk factors for young adults (e.g., worry, low self-esteem), the simple rationale, tips and exercises, and targeting habit change together make this variant of self-help potentially more efficient and engaging.



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There will be a self-component to educate and enhance EC knowledge, focusing respectively on EC perception and EC understanding. The intervention will be based on the assessment tasks developed as part of WP5 to assess EC knowledge (GERT; GEMEP; CEUT; GEMOK). Participants will receive immediate feedback on their answers to each item, including explanations why their answer is right or wrong. The test-based format is therefore used to support learning and psychoeducation.

To improve emotion perception skills, participants solve various psychoeducation tasks that involve video clips of emotional expressions that have previously validated correct responses (e.g., Geneva Emotion Recognition Test, GERT, Schlegel et al., 2014) and are provided feedback to improve skills with repeated training. The feedback will be detailed and designed to improve subsequent performance as the individual learns better to read emotional situations. The intervention will focus on training perception. Pilot work shows that a short computer-based training significantly improved performance on various emotion recognition tests, with effects enduring at least 4 weeks, and transferring to increased co-operation with a stranger (Schlegel et al., under review).

To improve emotion understanding skills, participants solve various psychoeducation tasks that involve realistic emotional scenarios that have already validated correct responses from our previous research and are provided feedback to improve skills with repeated training. The feedback will be detailed and designed to improve subsequent performance as the individual learns better to understand emotional situations and how an emotion can be regulated by changing each of the emotion components. Vignettes may be presented as animated scenarios to make more engaging and game-based.

### **Non-personalised digital self-help using generic CBT principles (active control group)**

The active control will be a non-personalised digital self-help based on generic principles derived from cognitive behaviour therapy (CBT) for promoting mental well-being and for preventing poor mental health. This self-help app will use well-established generic cognitive-behavioural principles, including tips, advice, strategies and psychoeducation including on behavioural activation to increase positive activities, spotting and challenging negative thoughts, relaxation, and positive psychology exercises, proven in RCTs to reduce symptoms of depression and anxiety and to promote well-being in young adults via online delivery (Clarke et al., 2015; Hetrick et al., 2016). It will be delivered via an app using the same features and structure as the personalised EC self-help to make the interventions as similar and as consistent in delivery as possible. The digital CBT self-help is designed to be a generic self-help intervention to help with emotional difficulties and non-specific stress (i.e., it does not target a specific disease).

The reasons for delivery via app are:

(1) **common assessment /engagement with app** - This fits with the intention for some assessment (e.g., self-assessment) and ESM (e.g., the rumination assessment) to be given to all participants via the app so we need to have a common delivery vehicle - otherwise the CBT arm would be being asked to switch between app and internet. It also gives a rationale for participants to use the app as well as to keep them engaged in the study

(2) **matched delivery** - we could deliver generic CBT self-help via a website but then this would be a different format from the modality used to deliver the personalised digital EC self-help. This would make a direct comparison difficult and raises the potential issue that any differences in effects could be due

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to means of delivery rather than the intervention content or personalisation. It is good trial practice to minimise the differences between treatment arms except to key content or structural elements -we already have differences in content and personalisation between EC and CBT so it would be good to minimise this. This is particularly important in this context when it appears that young people's access to digital material is increasingly through a mobile phone and thus it would be good for all to access through the same portal. We also know that there can be high rates of attrition from digital delivery - using the same means of delivery for both personalised EC self-help and self-help CBT should mean that equivalent rates of drop-out and attrition are more likely across the interventions, minimising this as a risk. The argument for making the interventions fit into the fabric of everyday life is true for both EC and CBT. In other words, any limitations (or strengths) of the app will apply equally to both. There is thus benefits in using a similar instantiation of the CBT self-help.

(3) **first major test** - despite the extensive evidence for internet CBT, and the growth in CBT apps, the evidence for CBT self-help apps is very small especially for prevention and promotion of wellbeing and only based on small studies - because our study includes a monitoring control condition, we can therefore test both the potential benefit of personalised EC self-help vs CBT self-help and passive controls, as well as the effect of a CBT app against the monitoring control.

(4) **feasibility** - the structure and architecture we have agreed for the EC interventions maps well for CBT self-help - i.e., the menu of dashboard, self-assessment, visualisation, videos, plans, and tools, and thus it would be efficient of time, resource, and programming to deliver the intervention this way - i.e., as one additional configuration within the app. Preparing this would therefore require us to map out detailed psychoeducation scripts for animations/videos, and to work out relevant tools to include e.g., a thought challenging tool, a positive activity tool etc. The basic functionality programmed for the EC app would support this – it would mainly require new content.

The digital CBT self-help app will include the default self-monitoring features (including a regular daily mood rating; emotion diary, and option for more detailed ecological momentary assessment), which will be the usual practice self-monitoring control.

In terms of theoretical action components, there is considerable evidence from reviews and meta-analyses that CBT interventions can be effective at preventing anxiety and depression, in adults (Cuijpers et al., 2008; van Zoonen et al., 2011) and more specifically in adolescents and young adults (Rohde et al., 2015, Current Opinion in Psychology). Central to these interventions are behavioural activation focused on increasing engagement in activities that elicit positive reinforcement or avoid negative reinforcement, and on identifying pessimistic thoughts and substitute more realistic cognitions for counter-productive ones. Evidence-based treatment protocols (from clinical trials) for the treatment of anxiety in children and adolescents have particularly focused on exposure, relaxation, cognitive, psychoeducational-child treatment elements (Chorpita and Daleiden, 2009). Evidence-based treatment protocols (from clinical trials) for the treatment of depression in children and adolescents have particularly focused on cognitive, psychoeducational-child, maintenance, activity scheduling, problem-solving, self-monitoring, goal setting, relaxation, and self-reward elements (Chorpita and Daleiden, 2009).

There is growing evidence of the efficacy of smartphone-based mental health interventions for depression (Firth et al., 2017) – finding that smartphone apps significantly reduced depression relative to controls ( $g = 0.38$ , 95% CI 0.24-0.53) (smaller for active controls –  $g = 0.22$ , 95% CI 0.10-0.33), but not yet tested directly for prevention.

Examples of apps include:

- (a) the Mood-Hacker mobile app, a self-guided intervention to use CBT skills in working adults with mild to moderate depression (Birney et al., 2016 JMIR) (control condition vetted websites on depression) [n=150 each condition] [app used an average of 16 times (SD 13.3) over 6 weeks.

App reduced depression significantly more than control. The Moodhacker app is based on the Coping with Depression (CWD) programme plus positive psychology strategies, which has been validated for prevention, different populations and in guided self-help intervention (Cuijpers et al., 2009, Clin Psychol Rev). Strategies included are mood and positive activity planning and tracking, cognitive restructuring, mindful self-awareness, gratitude expression, and identifying and using strengths, optimised for a brief daily interaction. It was a 6-week intervention, information delivered through daily emails to engage users, in app messaging and articles and video library, including mood and activity monitor with visualisation screen, list of activities to increase provided (social, physical, success), journaling feature.

- (b) iPST and EVO apps (Arean et al., 2016, JMIR), in trial of 626 adults with mild to moderate depression randomised to EVO –cognitive training app [video game designed to modulate cognitive control abilities]vs iPST based on evidence-based problem-solving psychotherapy [7-step process to create an action plan based on evidence-based treatment, Malouff et al., 2007; Bell et al., 2009 Clin Psych Review] vs. Health Tips, a treatment control. 58% did not download their assigned intervention app. For those PHQ>10, cognitive training and problem-solving apps greater effects on mood than information control. Email /SMS reminders sent by research item if assessment/assignment not completed or app not used in 72 hrs. Those who used their app at least once used on average 10.78 (SD 11.44) times. Use typically wanes over first 2 weeks [need to consider solutions to this – reminders, app shifts over times, boosters over months]

It is therefore clear that the CBT intervention will need to include some psychoeducation about the relationship between thoughts, feelings, behaviours - e.g., interpretations influence emotions; being more active improves mood; reducing avoidance improves mood; and some guidance and advice and tips regarding the benefits of the following approaches: behavioural activation (identifying positive activities; making plans to do them, i.e., activity scheduling); spotting and challenging negative thoughts related to feeling low and feeling anxious, with some examples and illustrations, relaxation, and plans to tackle avoidance related to anxiety through exposure. It may also include some simple positive psychology exercises e.g., naming 3 positive things today, that have some evidence for efficacy through internet trials (Seligman et al., 2005)

The results of the trial will therefore test if personalised digital EC self-help outperforms a state-of-the-art non-personalised generic digital self-help. However, we cannot determine from this trial whether the benefits are due to personalization and/or the EC focus, and subsequent research (e.g., comparing personalised versus non-personalised EC interventions) would be necessary to unpack the construct validity of the intervention. Nonetheless, this is the appropriate first step because (i) the primary objective is to develop and test the most efficacious option (whichever that is found to be), with the priority to maximise mental well-being in young adults; (ii) there is limited value in unpacking its mechanism if the new intervention does not improve on existing options.

### **Self-Monitoring Usual practice control (*Usual practice control group*)**

Usual practice control is carrying on in the prospective cohort, i.e., receiving usual care plus the default basic version of the app, featuring self-monitoring and the baseline assessment and 1, 3 and 12 month assessments delivered via the screening website.

Self-monitoring will include daily mood ratings and the opportunity to record events in the event diary and an ecological momentary assessment option (Mood Tracker) for more detailed analysis of mood and activity and situation relationships. This is monitoring for the purpose of understanding general emotional state and well-being, does not include any specific symptom measures and effectively replaces written diary/logs. Usual practice as received by the young person outside of the trial, may include no provision of intervention, local provision of interventions, support from their GP/family doctor or local health services or youth services, or within their educational institution (e.g., well-being service at university; support and welfare staff at school). This is the appropriate comparator because the primary question is determining whether the addition of the personalised digital EC self-help and the

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non-personalised digital CBT self-help promotes wellbeing and prevents poor mental health in the sample relative to what happens normally. The nature of usual practice will be monitored and assessed by questionnaires at each follow-up assessment, determining what treatment and services participants have received since the last assessment.

## **8.10 Trial restrictions**

Participants will need to be aged 16 to 22 and resident in UK, Spain, Germany and Belgium. Participants with current or past depression, suicide risk or a past history of psychosis or mania at baseline will be excluded from all trials. Participants aged 16/17 from, Belgium or Germany will need to have parental permission to consent to take part in the trial. Participants will need to have basic literacy in English, Spanish, German, or Dutch, and access to a smart phone.

## **8.11 Assessment of compliance with treatment**

There will be regular downloads of the MONSENSE data which will be compiled in a data base hosted by EXCTU. This will be to safe guard the data and will be in .json format. The trial manager will monitor the progress of participants in each version of the app so that any problems can be identified, to investigate which pages of the app are and aren't not being accessed and which pages were last viewed. This should help identify any key areas of technical difficulty or off-putting content or where improvements in functionality are needed. Participant queries relating to app content will also be reviewed and summarised for the TMG. 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.

# **8. ADVERSE EVENTS**

## **Participant welfare and safety**

There is no known health risk associated with any of the assessments or self-help. The risk concerning participation in this study is believed to be low. Further, we anticipate that the self-help will reduce vulnerability and the risk for developing poor mental health 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.

Because the ECoWeB-PROMOTE and ECoWeB-PREVENT trials are examining well-being promotion and prevention of poor mental health, the initial screening process will exclude anyone with current or past self-reported history of 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.

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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 rumination self-help intervention and indicated reductions in poor mental health over 12 months, with no serious adverse events reported: as such, this component of 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 (e.g., youthinmind.info; Samaritans; General Practitioners; Teléfono de la Esperanza; Telefonseelsorge; websites providing contact details of psychotherapists and psychiatrists, as relevant; websites providing clinically approved advice for mental health conditions).

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.

The main indicators of harm will be the completion of questionnaires by the participants at all 4 assessments (baseline, 1 month, 3 month, 12 month). Questionnaires will be automatically screened for signs of severe distress (for example, defined as scores above 20 on PHQ-9 for depression or 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, relevant charities; e.g., website link to the Samaritans in the UK, link to Childline; to the "Teléfono de la Esperanza" in Spain; to websites providing contact details of psychotherapists and psychiatrists in Germany: <http://www.bptk.de/service/therapeutensuche.html>; portal site for mental well-being in Flanders <http://www.geestelijkgezondvlaanderen.be/> and the register of clinical psychologists in Flanders <http://www.vvvp.be/psycholoog/zoeken>). Other indicators would be report of worsening symptoms or suicidality in direct contact from participants to the research team.

For all participants (because all participants receive an app), to further assess potential harms, we will include brief open questions to assess potential harm from the interventions (e.g. "How you have any problems with the app? Has any aspect made you feel worse?"), whilst minimizing participant burden (at 3 and 12 months assessments). Potential adverse events will also be assessed using additional questions relating to hospitalisation and emergency care within the ADSUS questionnaire.

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. In addition, there will be a help option built into the app, where users can seek information on commonly occurring symptoms and difficulties and be directed to relevant contacts and links.

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 16). Each site will have a designated senior clinician(s) [clinical psychologist or consultant psychiatrist] 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 will contact the participants (by email, telephone) to review situation, provide guidance and offer to write a referral letter, subject to participant consent (see Appendix 16 for a copy of the letter). 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 the table below.**

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 including death, suicide attempt, self-harm, serious accident or violent incident, referral to crisis care or admission to psychiatric hospital. The following definitions are therefore adapted in light of this.

**Table 15 Definitions of Events**

Term	Definition
<b>Adverse Event (AE)</b>	<p>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.</p> <p><i>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.</i></p>
<b>Adverse Reaction (AR)</b>	<p>Standard: An untoward and unintended response in a participant to an investigational medicinal product which is related to any dose administered to that participant.</p> <p>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.</p> <p>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.</p> <p><i>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.</i></p> <p>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.</p>

		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.
<b>Serious Adverse Event (SAE)</b>		<p>Standard: A serious adverse event is any untoward occurrence that:</p> <ul style="list-style-type: none"> <li>• results in death</li> <li>• is life-threatening</li> <li>• requires inpatient hospitalisation or prolongation of existing hospitalisation</li> <li>• results in persistent or significant disability/incapacity</li> <li>• consists of a congenital anomaly or birth defect</li> </ul> <p>Other 'important events' may also be considered serious if they jeopardise the participant or require an intervention to prevent one of the above consequences.</p> <p>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.</p>
<b>Serious Adverse Reaction (SAR)</b>		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.
<b>Suspected Unexpected Adverse Reaction (SUSAR)</b>	<b>Serious Reaction</b>	<p>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:</p> <ul style="list-style-type: none"> <li>• 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 its licence. If it is being used off label an assessment of the SmPCs suitability will need to be undertaken.</li> <li>• in the case of any other investigational medicinal product, in the investigator's brochure (IB) relating to the trial in question</li> </ul> <p><i>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:.</i></p>

## Adverse event reporting and management

### 9.2 Operational definitions for (S)AEs

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These have been provided in section 9.1

### **9.3 Recording and reporting of 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 2 working days to the trial sponsor. If these are also classed as unexpected they will be reported to the relevant ethics committees. 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 12month post baseline follow-up. Data on any adverse events will be collected by a member of the research team at each assessment.

### **9.4 Responsibilities**

Researchers at each trial site to check for AEs and ARs when participants complete digital treatment / follow-up, potentially in response to automated feedback from website

1. Principal Investigator (PI) for each trial site is responsible via liaison with research team at trial site for: Ensuring that all SAEs are recorded and reported to the sponsor within 2 working days of becoming aware of the event and provide further follow-up information as soon as available. Ensuring that SAEs are chased with Sponsor if a record of receipt is not received within 2 working days of initial reporting.
2. Ensuring that AEs and ARs are recorded and reported to the sponsor in line with the requirements of the protocol.
3. Immediate review of all SUSARs.
4. 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 trial manager)

1. Central data collection and verification of AEs, ARs, SAEs, SARs and SUSARs according to the trial protocol onto a database.
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. Expedited reporting of SUSARs to the Competent Authority (MHRA in UK) and REC within required timelines.
5. Notifying Investigators of SUSARs that occur within the trial.
6. Preparing standard tables and other relevant information in collaboration with the CI and ensuring timely submission to the MHRA and REC.

Trial Steering Committee

In accordance with the Trial Terms of Reference for the TSC 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.



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## **9.5 Notification of deaths**

All deaths will be reported 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.

## **9.8 Reporting urgent safety measures**

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

## **9.9 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**

The overall sample size for EcoWeb is predicated on recruiting an overall cohort of potential participants that will have adequate sample size to allow us to recruit to each of the two RCTs (ECoWeB-PROMOTE; ECoWeB-PREVENT). Once these trial sample sizes are determined, the size of an overall cohort of potential participants will be selected using expected proportions of potential participants that will be eligible for each of the two trials.

Each of the two trials includes the following three arms: (i) usual practice including self-monitoring plus offer of personalised digital EC self-help; (ii) usual practice including self-monitoring plus offer of non-personalised digital CBT self-help; and (iii) usual practice including self-monitoring (i.e., continuing in cohort).

The following sample size calculations for each trial are based on a 2-arm comparison and three analytical contrasts (arm i vs arm iii or arm ii vs. arm iii or arm i vs. arm ii), with no adjustment for multiple testing (for example, by adjustment of the alpha threshold). All sample size calculations are based on a 2-sided test with 90% power, an alpha threshold of 0.05, and 40% attrition at 3-month follow-up (e.g., Topper et al., 2017).

### **10.1.1 Sample size calculation for ECoWeB-PROMOTE**

The sample size for the ECoWeB-PROMOTE trial was calculated based on WEMWBS, the primary outcome for ECoWeB-PROMOTE. The minimum clinically important difference (MCID) for WEMWBS was taken to be 3.0 points. A reduction in 3 points was recommended as the minimum meaningful change in the guidelines for the measure (Putz et al., 2012); it was found to be the smallest difference from a study of the WEMWBS responsiveness and the lowest value greater than standard error of measurement (Maheswaran et al. 2012) and was the difference found between a minimal self-help online CBT treatment

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and waiting list control at the 12-week endpoint for adults (Powell et al., 2013). The standard deviation (SD) for change on the WEMWBS varies from 6.0 to 11.3 (Maheswaran et al., 2012); a conservative SD estimate of 11.3 was used for calculation of sample size.

Prior to accounting for attrition, 300 participants per arm are required. Accounting for attrition of 40% at the 3-month primary follow-up point, 500 participants per trial arm are required; with 3 trial arms this gives a total sample size target for the ECoWeB-PROMOTE trial of N=1500.

#### **10.1.2 Sample size calculation for ECoWeB-PREVENT**

The sample size calculation for ECoWeB-PREVENT is based on the primary outcome, PHQ-9 score, which has an established and published MCID of 2.59 and SD of 5.4 (Löwe et al., 2004). Prior to accounting for attrition, 93 participants per arm are required. Accounting for attrition of 40% at 3-month follow-up, this requires 155 participants per arm; with 3 trial arms this gives a total sample target for the ECoWeB-PREVENT trial of N=465.

#### **10.1.4 Sample size for recruited cohort prior to trial allocation**

Participants (eligible for one of the trials and consenting to participate) will be recruited via the project website; these participants will form a 'recruitment cohort'. The estimated proportions of participants by trial within the recruited cohort are 70% for PROMOTE and 30% for PREVENT. We require 1500 or more participants for ECoWeB-PROMOTE; assuming 70% of the recruitment cohort will be eligible for ECoWeB-PROMOTE, we will require 2142 potential participants to comprise the recruitment cohort. Assuming that 30% of this recruitment cohort will be eligible for ECoWeB-PREVENT, this will yield 642 potential participants in the recruitment cohort for ECoWeB-PREVENT, exceeding the required sample size for this trial.

#### **10.01.5 Revision of sample size due to technical difficulties with the app**

In amendment 8 (dated 05.07.21) to the original trial protocol, the sample size for the trial was increased to 3599 plus due to the need to replenish 1457 participants. The app providing the intervention ran into technical difficulties during February, March and April 2021 and was offline for all participants for a month due to a fire at OVH, the cloud server company supporting the app, badge (reward data) was out of date for the majority of participants for 2 months and around 900 app accounts were lost including all data on the app. New participants were recruited in to the trial on a new Monsenso system and those who lost accounts were invited to set up a new app on this system. A proportion chose to do so, but the majority did not. A full explanation of the revised sample size calculation can be found in the statistical analysis plan version 1.6 dated 24.06.21, which was approved by the independent Trial Steering Committee. Outcome measure data was not lost as this was collected and stored on a separate system.

#### **10.2 Planned recruitment rate**

Recruitment will take place over up to 52 weeks across 4 sites. It is estimated that an average of 14 potential participants (eligible for one of the trials and consenting to participate) will be recruited per site per week, leading to expected recruitment of 2912 potential participants (assuming recruitment across all weeks). This exceeds the required sample size for the overall recruitment cohort (2142 potential participants). The planned recruitment rate was dramatically increased for the last 2 months of recruitment to cope with the change in sample size.

#### **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 – for full details see project SAP whose details supercede this. The statistical analysis for each trial will follow the same broad guidelines; any adaptations for each trial individually we reported

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in the detailed SAP. 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 TSC 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 a self-help psychological intervention, 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) we will ask them if they are happy to allow us to retain the data already provided to the trial; if the participant does not consent to retention of data, the data will be destroyed.

### **10.3.2 Primary analysis**

The primary outcomes (WEMWBS (ECoWeB-PROMOTE); PHQ-9 (ECoWeB-PREVENT) 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 three treatment contrasts ((1) usual practice plus personalised digital self-help EC vs. usual practice alone; (2) usual practice plus non-personalised automated digital CBT self-help vs. usual practice alone; (3) usual practice plus personalised digital self-help EC vs. usual practice plus non-personalised automated digital CBT self-help) using linear modelling. 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 minimisation variables (age, gender, country). Furthermore, we will adjust for any baseline participant characteristics that are substantively unbalanced at baseline (defined as a difference  $\geq 10$  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 secondary outcomes (occurrence of major depressive disorder; generalized anxiety disorder) will be reported as proportions and analysed using logistic regression.

### **10.3.3 Secondary analyses**

A number of secondary analyses will be conducted.

#### **1. 12-month follow-up comparison**

Primary and secondary outcomes will be compared at 12-month follow-up using the statistical approach outlined above.

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## 2. Repeated measures comparison including all timepoints

Primary and secondary outcome measures will be compared at all follow-up timepoints (1, 3, 12 months) using repeated measures analyses, including all participants with data available for at least one of the three follow-up timepoints.

## 3. Differential adherence analysis

Differential adherence within the active treatment arms is anticipated, which could impact the outcomes. Ideally, we wish to compare participants who adhere to their intervention with those in the comparator arm who would also have adhered to the treatment had they been allocated to it. To address this issue we will undertake a complier average causal effect (CACE) model, using a 2-stage least squares instrumental variable regression model. Such models will be performed for the continuous primary and secondary outcomes at 3- and 12-month follow-up using observed data only, and will include the covariates adjusted for in the linear regression models. The CACE analyses will be considered as secondary analyses. The definition of a 'complier' will be: (i) complete at least one Challenge (some psychoeducation) and at least four Challenges completed or ten Tools used (to capture practice) OR (ii) (to capture combined usage) at least ten Challenges or Tools completed (any combination), including at least one Challenge and one Tool. (The definition of a 'complier' may be subject to further revision.)

## 4. 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 minimisation 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. Imputation models will be informed by treatment arm, baseline scores, other covariates to be included in the model, and other baseline characteristics found to predict outcome or propensity for missingness (logistic regression models will be used to investigate the associations between baseline characteristics and missingness). Regression models using the imputed datasets will be performed using the same methods as described for the ITT population. Analyses using imputed data will be considered as a secondary analysis.

## **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 minimisation variables (age, gender, country).

To investigate differential treatment effects across subgroups of participants, we will perform a series of models, for the primary outcome only at 3-and 12-month follow-up, including an interaction term between treatment arm and the participant characteristic (as well as the other covariates to be adjusted for; each model will include one interaction term only). The participant characteristics to be investigated for differential treatment effects are age (continuous and dichotomised as for the minimisation algorithm), country and gender. The interaction terms will be reported as coefficients and 95% confidence intervals, with a global p-value. It is acknowledged that these analyses will have limited statistical power, and hence are exploratory in nature, and the results should be viewed with caution.

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## **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 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 three treatment allocations (personalised EC self-help vs. online CBT self-help; personalised EC self-help vs. usual practice; online CBT self-help vs. usual practice). 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 Mediation analyses**

Quantitative mediation analyses will be described in the process evaluation analysis plan.

Mediation analyses will test the hypotheses that the personalised EC intervention is effective by changing unhelpful habits and improving EC skills. Each of these potential mediators of the primary outcome is a continuous variable, assessed via the EC instruments at 1-, 3- and 12-month follow-up, potentially examined as latent variables/factors from a factor analysis.. Analyses will include the use of instrumental variables to account for effects of unobserved confounding on mediators (Dunn et al., 2005).

## **10.8 Economic evaluation**

### **Economic analysis**

The economic analysis will take a societal perspective and undertake a cost-consequence approach. Because all the resources used, costs, and outcomes are transparently listed in the cost-consequence analysis, decision makers can select the information that is of most interest to them. Furthermore, the choice of cost-consequence analysis supports current approaches used by healthcare decision-makers to value the efficiency of healthcare interventions across Europe (Angelis et al., 2017).

Unit costs of health and social care will be taken from appropriate national publications to reflect differences in costs between countries (for example, Curtis & Burns, 2018). Productivity losses will be valued using the human capital approach (Koopmanschap & Rutten, 1996). Wage rates for each country will be derived from European sources such as Eurostat. Responses to the EQ-5D-3L will be converted to utility values using the EuroQoL general population tariff values for each country.

Within country analyses of the differences between the trial arms will be undertaken. Although the distribution of costs is commonly skewed in populations of this kind, analyses will compare mean costs between groups using standard parametric regression models adjusted for minimisation variables and baseline costs. The robustness of the parametric tests will be confirmed using bias-corrected, non-parametric bootstrapping (Efron & Tibshirani, 1993; Barber & Thompson, 2000). As with primary and secondary outcomes, between group differences in costs and EQ-5D-3L will be presented as means and 95% CIs using STATA v14.2.

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Given the differences in cost structures (health and social care, and wage rates) and differences in the population tariffs between countries no formal analyses of differences between costs and utility values between countries will be undertaken. However, the differences between the number and type of resource use and days away from work and employment will be examined.

## **10.9 Implementation Science**

As part of the research there will be qualitative investigation of participant experiences using the App. A random sub-sample of participants will be contacted by our collaborating research team at the University of Oxford (ECoWeB WP8) to see if they would be willing to take part in an additional interview 3 and or 12 months after being randomised into the trial. All participants are asked if they would be willing to be contacted about future/additional research in consent form B. The ECoWeB WP8 information sheet and consent form C have been uploaded for review with this protocol.

## **11 DATA MANAGEMENT**

### **11.1 Data collection tools and source document identification**

Database management, data curation and sharing will be supported by UNEXE and EXCTU. Efficacy/effectiveness parameters will be directly and automatically entered into an SQL database programmed by Exeter CTU. At assessment participants will directly complete electronic questionnaires and tasks online using the Qualtrics website 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 EXCTU. The App data collected from participants will be collected from MSS through an https website

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. 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 ECoWeB 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**

A separate data management plan accompanies this trial protocol.

### **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.



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## 11.4 Archiving

Source documents, and trial-related electronic and other data will be stored safely and in accordance with the requirements of the Data Protection Act (1998), for a minimum of five 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.

## 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 trial manager to this role, who will provide monitoring across sites and management of the centralised recruitment and data management systems, and support and evaluate the quality and integrity of study sites' practices and protocol adherence to applicable regulations. Additionally, the trial manager will manage study progress by tracking regulatory submissions and approvals, recruitment and enrolment, data completion, and data queries (generation and resolution). Each recruitment site will also have a dedicated research associate dedicated to trial recruitment and monitoring. A manual of monitoring will be prepared, and all the staff across all countries will adhere to the same procedures.

Central vigilance and the reporting of Serious Adverse Events (SAEs) will be provided by UNEXE (Part. 1) following the Good Vigilance Practices (GVP). A special SAE-Form will be part of the eCRF. Safety and tolerability will be evaluated by recording AEs and SAEs throughout the study.

### Quality assurance procedures for the ECoWeB-PREVENT and ECoWeB-PROMOTE Clinical Trials (WP6 and 7)

The appropriate design of a clinical trial protocol ensures the safety, rights and well-being of participating patients. The clinical protocols for ECoWeB-PREVENT and ECoWeB-PROMOTE trials will be finalised at Month 14 after being reviewed and approved by the UNEXE ethics board and relevant ethical review committees at each participating institution. The Sponsor will be responsible for providing final version

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of the clinical protocol to its partners. 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. This initial data management plan will necessarily be provisional as details of measures and procedures will be contingent on developments in WP2-5. The proper communication pathways will be defined upfront by UNEXE in order to keep all partners informed about the status of the studies.

UNEXE will have overall responsibility for the monitoring of the delivery of the clinical studies across the internet website and app across all participating countries 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). A manual of monitoring will be prepared. All the Research Associates at each site, whatever the country, will work with the same procedures. The majority of this process will be automated through the use of the website and app 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 current ECoWeB proposal is dedicated to investigating the mechanisms and determinants of mental well-being and mental health in young people and proposes an innovative digital Emotional Competence approach to promote mental health and well-being in this population. This project builds on evidence that emotional competence or the lack of is implicated in mental well-being and mental health, and on evidence that manipulating aspects of emotional competence, such as use of unhelpful regulation in the form of rumination, can influence mental health and well-being.

To that end the research activities of ECoWeB include: Collection and processing of personal data, including sensitive personal data (i.e. health), and tracking of participant's mood, emotional competence skills and well-being over time; - Intervention programme (the selected participants undergo personalised digital EC self-help or a non-personalised digital CBT self-help or self-monitoring (usual practice) control.

The ECoWeB Consortium will address scrupulously all the ethical, legal, social, and safety issues raised by its research activities. We approach these with considerable existing expertise and also a desire to continually improve our ethical appreciation of the work we do.



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We note the urgent need to conduct research in children and young people in order to overcome equipoise and establish the evidence base for potential preventative interventions and treatments and we endorse the conclusion of a recent Lancet editorial (2015): “It will always be easier to say ‘no’ to research with children on the grounds that it’s too difficult, but we should challenge the idea that it is acceptable to continue to offer health care to children without seeking to improve the evidence base for many of the treatments provided”

### **13.1 Research Ethics Committee (REC) review & reports**

Ethical considerations have been taken into account from the design of a study, to the conduct and even to the reporting of study results. International Conference on Harmonisation (ICH) has entered ethics into clinical studies, determining sponsor and investigator responsibilities and developed the concept of Good Clinical Practice (GCP), which provides guidance to investigators that can result in a common approach to clinical trials performed in multiple countries. GCP compliance provides assurance that the reported data are accurate, and that the rights, integrity, and confidentiality of participants are protected.

Standard Operating Procedures (SOP) will be written and reviewed by the consortium according to the ethical standards of the Helsinki Declaration of 1975 on GCP, as revised in 2013 by the ICH.

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.

Each participating centre to the trials within ECoWeB is responsible for obtaining the ethical and regulatory authorisations for their study according to the laws and procedure in their country.

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 in the ECoWeB study will be free and voluntary and electronically-signed informed consent will be obtained from each participant prior to entering the study (and, where relevant, from one or more legal guardians). 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 the personal data protection laws in the various EU countries. 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 all centres 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.

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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.

ECoWeB investigators will conduct all clinical studies 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 and site Universities and, if necessary, the MHRA.

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 (note that amendments may also need to be reviewed and accepted by the MHRA and/or NHS R&D departments before they can be implemented in practice at sites)
- all correspondence with the REC will be retained in the Trial Master File/Investigator Site File
- an annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the trial is declared ended
- it is the Chief Investigator's responsibility to produce the annual reports as required.
- 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

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## 13.2 Peer review

The project received favourable ethical review from the European Commission for grant award.

## 13.3 Public and Patient Involvement

### Youth Advisory Board (YAB)

In order to 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, the ECoWeB project will create four local (in each of the study languages: English, German, Spanish and Dutch) and one international Youth Advisory Board (YAB) that will participate in key tasks of the project:

- Design of the EC paradigms (WP3-5)
- App design and functions (WP2-6)
- Issues of consent, confidentiality, privacy (WP6)
- Recruitment and access to app strategies (WP6)
- Providing insight into the experiences and concerns of young adults (WP8)
- Dissemination strategies (WP9)

The YABs will have representatives of the two age ranges (16-18) (19-22), male and females, and the four languages of the study (English, German, Spanish, Dutch) and include members from vulnerable and migrant backgrounds to ensure these views are represented. The YABs will meet ahead of key decisions making points in the project in order to make the most of this resource.

Organisations for young adults will also be consulted for the design of the prospective cohort study (WP6) and the clinical trials (WP7) in order to provide the consortium with comments and recommendations from the perspective of those with relevant lived experience, including any ethical questions. Young adults (e.g., via Youth 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. The consortium already have existing collaborative links e.g., with Young Minds in the UK, and AITANA in Spain.

## 13.4 Regulatory Compliance

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

## 13.5 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

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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 all recruitment materials and 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 e.g:

*'This trial is recruiting participants from UK, Spain, Germany and Belgium who are aged 16 to 22. Unfortunately if you are outside of this age range or not resident in these countries then we are unable to invite you on to the trial. The aim of the trial is to test interventions aimed to improve wellbeing and reduce the likelihood of depression. If you are currently depressed or have a history of psychosis or mania then this intervention will not be right for you and we urge you to contact your medical practitioner for help and support for this.'*

All advertising will also only be targeted at those meeting the age criteria to reduce the numbers of those outside of the age group being recruited. This is possible by setting online adverts to only those of the specified age group and residency and promoting recruitment where only this age group study, work or enjoy leisure activities. There will also be no recruitment through any medical practitioners or services.

Prior to asking for consent or starting the assessment, the screening website asks for date of birth and country of residence. Post consent the screener asks a series of questions designed to check if the participant meets any of the exclusion criteria. The LIDAS questionnaire is well validated for identifying a history of depression and there are follow up questions to check for depression and use of antidepressant medication. The screener asks for date of birth rather than age to try to discourage anyone outside of the age group from taking part and will be asking for parental consent from anyone from Germany or Belgium who is aged 16/17. It will also not be possible to click the back button to change the data in the date of birth field. It is not possible to block participants from typing in the URL again and retuning to the screener or multiple attempts from the same IP address because often large institutions have the same IP address. Collection of IP address for any purpose prior to consent would also not meet GDPR standards.

In the UK young adults aged 16/17 are legally able to consent for themselves.

We recognise that it is possible that young people outside of the specified age range will choose to not be honest about their age in order to take part in the trial. However, formal checks of the age of participants are likely to not be feasible, economical and to impact on overall recruitment and in particular skew recruitment from particular backgrounds of interest such as migrants and refugees. On a GDPR basis, we cannot ask individuals to provide copies of identification documents and this would be a major deterrent to participation given the focus on anonymity and confidentiality stressed by young users (YAB). Past experience has indicated that the majority of participants are accurate about their age and that we can trust the veridicality of self-reporting. Participants will be repeatedly reminded about the age limits and their rationale during the recruitment and consent process and advertising will be focused on the appropriate age group, reducing the likelihood of inappropriate groups accessing the intervention. We will repeatedly ask the date of birth of participants as a manual check on consistency of response/age.

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.

## **13.6 Notification of Serious Breaches to GCP and/or the protocol**

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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 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.

## **13.7 Data protection and patient confidentiality**

### **Data protection**

The conduct of the project will comply with the Directive 95/46/EC of the European Parliament and of the Council of Europe dated 24th October 1995 and with Regulation (EU) 2016/679 ([http://ec.europa.eu/justice/dataprotection/reform/files/regulation\\_oj\\_en.pdf](http://ec.europa.eu/justice/dataprotection/reform/files/regulation_oj_en.pdf)) which replaces it, on the protection of individuals with regard to the processing of personal data and on the free movement of such data. Namely, it will comply with regulations transposing this directive at the national level (e.g. Data Protection Act DPA number g0027154 in UK; German Federal Data Protection Act in Germany; Law on Data Protection [LOPD] in Spain; Privacy Act in Belgium). The EU Directive concerns the protection of individuals with regard to the processing of personal data and on the free movement of such data. Adequate measures to ensure data protection and confidentiality will be duly taken into account by the project partners. Local, national, and international 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 two 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 assessment website. A third MSS database will store all data collected as part of the project directly from the app. This data will be stored without any identifying information or contact details, and will be linked to the MSS account ID for each participant. The codes linking contact information with the databases containing outcome will be destroyed following the end of data cleaning and preparation for analysis. 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 and Spain; adaptations will be made as necessary for specific local ethical requirements.

The site research teams will 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. Site 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 site

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researchers are not given the allocation details to maintain blind. A log of contact with recruiters, potential and actual participants will be held in local secured data management systems in each country.

**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, hand held devices, digital cameras or other imaging equipment even if they are password protected. An encrypted memory stick may be used if required.

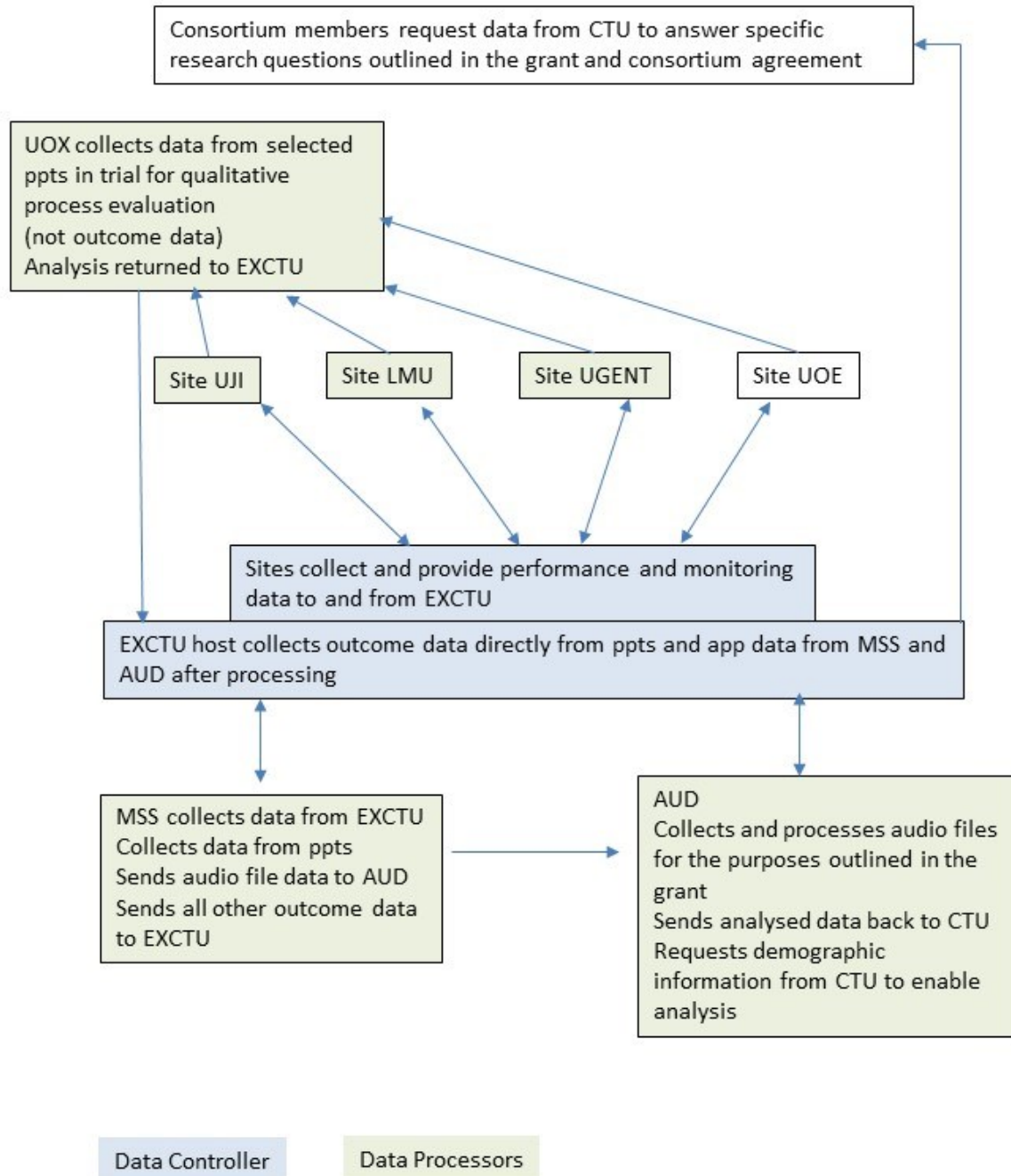
Data transfer between UOE and MSS:

The email address and version/configuration of the App the participant should receive will be encrypted and sent securely to MSS once the participant has consented to join the trial and been randomized. This will be an automated process through the API. MSS need the email address so that they can email a link to allow the participant to access their version of the App and so that the participant can reset their App password if they forget it.

Monsenso hosts and operates its solution on encrypted servers within the EU. The system complies with the EU 2000/58/EC & 2002/58/EC Directive on privacy and electronic communications and the EU Directives 95/46/EC and with the superseding directive 2016/679 GDPR (and Danish Act on Processing of Personal Data implementing EU Directive 95/46/EC). In terms of the Directive 95/46/EC, Monsenso will be a Data Processor, and the UOE as sponsor will be the Data Controller. Data Processing agreements between the data controller UOE and the trial sites and qualitative research teams (UOXF, DJI) will be made, stipulating in what manner they should process data for the purpose of the ECoWeB project. Data controller to processor agreements will also be in place between UOE and MSS, UOE and AUD, and if directed by the data controller, there will be an agreement between MSS and AUD. The data flow in the trials is described in the data flow diagram on page 93.



## Overview of Data Transfer for ECOWEB



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All data generated will be stored by UOE 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.

**Privacy by Design:** Privacy by design means that each new service or business process that makes use of personal data must take the protection of such data into consideration. An organisation needs to be able to show that they have adequate security in place and that compliance is monitored. In practice this means that privacy must be taken into account during the whole life cycle of the system or process development. Monsenso is both ISO 27001 and 13485 certified. ISO 27001 is a specification for an information security management system (ISMS). An ISMS is a framework of policies and procedures that includes all legal, physical and technical controls involved in an organisation's information risk management processes. Combined with ISO 13485, which provides a practical foundation to address the Medical Device Directives, regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices, ensures the consistent design, development, production, security, installation, and delivery of medical devices that are safe for their intended purpose, throughout the Product Management Lifecycle.

Monsenso not only apply Privacy by Design, but also Privacy by Default, and therefore these approaches will be central to the current app. Privacy by Default simply means that the strictest privacy settings automatically apply once a customer acquires a new product or service. In other words, no manual change to the privacy settings should be required on the part of the user. There is also a temporal element to this principle, as personal information must by default only be kept for the amount of time necessary to provide the product or service.

### **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 the site of data collection will only be given access to de-identified data, and they must sign a declaration stating that they will adhere to EU data protection legislation. We plan to use the standard EU contract for transfer of personal data. We do not anticipate any sharing of data from the clinical trial with sites outside of the EU during the course of the project.

Personal data have to be deleted as soon as its processing purpose is expired. Within the project this will be as soon as no direct contact with the participants is necessary any more, which is effectively at the end of the project. In the case that a participant withdraws his or her informed consent, this person's identifying information will be deleted. The remaining information will be effectively anonymized.

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 (ten years in the UK and in Germany).

**Responsibility:** The University of Exeter as sponsor of the trial is the data controller, and the collaborating Universities and technical companies (MSS and AUD) are data processors. 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.



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Legal data transfer agreements will be written and signed between the data controller and data processors prior to any participant being recruited. 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 screening website, the Monsenso App and the Audeering website. The screening website will also email this policy to consenting participants with the information sheet and consent form. A common policy has been chosen to ensure that common standards for data protection apply across the different grant-holding partners in the ECoWeB consortium. Keeping this information (and data protection standards) common and in a format that the young adults can understand is key to making sure that they understand what data will be collected, why, where, when and how it will be stored.

### **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: <http://alf.exeter.ac.uk/share/s/uyGbdLMSQD-30UfzXNLSVA> 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 and consortium members in a secured manner (encrypted files via ftps/https servers).

### **Data Monitoring**

Data will be accessed by the trial 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 ECoWeB 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.

### **Data collection by smart phone**

ECoWeB will utilise a smartphone app to collect data from participants, with a focus on data that is actively and knowingly provided by participants via the app, whether in the form of answering questions, completing tasks in the app, or rating emotions, appraisals, and responses in response to time-sampling or event-sampling.

### **Audio recordings within the smart phone app**

Participants will be asked to consent to provide direct speech recordings (like a voice note) during a task in which participants voluntarily, optionally and knowingly describe an emotional event. This will enable the research team to analyse emotional states and appraisal processes from markers in the voice with the VocEmoApl technology. Acoustic features will be extracted from the voice files within the

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app and streamed to AUD. In addition, encrypted voice files that have been filtered and masked so that a person's voice cannot be identified will be streamed from the App to the AUD website. The voice recordings will be labelled with the date and MSS account number. The use of the voice recording and analysis is voluntary at every occasion of reporting an emotional event – participants can decline to do this without any consequences. Participants can request the deletion of the audio-files.

### **13.8 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. The two non-academic companies in the consortium (audEERING, Monsenso) have a potential future commercial interest in marketing and providing the app created and in exploiting the data collected, subject to IP agreements with other partners, but they are not directly involved in trial management.

### **13.9 Indemnity**

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

Appropriate insurance cover or equivalent to address their potential legal liabilities to participants in the trial will be held by each of the trial partners (UJI, Gent, LMU, audEERING, MSS).

### **13.10 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.

### **13.11 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 App will be used for at least one to two-month period following randomisation but it is available for use throughout the full 12 month period of their follow-up. Participants will be able to continue to have access to the App for at least the 12 months that they are in the trial (12 months from randomisation to final follow up).

### **13.12 Access to the final trial dataset**

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

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## 14 DISSEMINATION POLICY

### 14.1 Dissemination policy

There is an overall dissemination policy for the ECoWeB project (see details below), 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 jointly owned by the trial partners within the ECoWeB consortium (UNEXE as trial lead, lead for trial design, CTU, and trial analysis, and trial site and contributor to interventions; LMU as trial site and contributor to interventions; UGent as trial site and contributor to interventions; UJI as trial site, MSS and AUD as technical providers for digital interventions; UOXF as supporting qualitative activities), 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 (as a deliverable within the funded EC Horizon2020 grant), and made publically available on the trial website and via the funder. This will be published before the end of December 2021

(iv) Our publication policy stipulates that all potential publication plans need to be reviewed by the Project Steering Committee before release of data in order 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 include the following statement: "This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 754657 (ECoWeB)". Publications that tally with specific deliverables of the grant including the outcomes of the trial will be submitted to the funder as deliverables but the funder does not have review or publication rights of the data from the trial.

(vii) There are plans to notify the participants of the outcome of the trial, through a combination of a specifically designed newsletter, blog, vlog 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; the trial protocol will be available after June 2019 and sent for publication in 2019; the full trial report will be made publically available by the end of December 2021.

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## **Publications and Public Disclosures**

Due to the significance of the dissemination and exploitation activities in achieving the ultimate goal of the project, ECoWeB manages and coordinates its diverse dissemination activities through a dedicated work package (WP9). A coordinated communication, dissemination and exploitation of the project results is a key objective for all partners during all phases of the project.

From the start of the project, WP9 will develop an external website and a dissemination plan (which will be updated mid-way through the project). WP9 will also provide a Tool Kit of materials to support:

Dissemination efforts by all partners ensuring a consistent look for the project, building awareness and establishing reputation across all institutes, specialities and geographies.

Co-ordinated central communications activities at major meetings and traditional and social media activities.

UNEXE, UJI and the ECoWeB SC will monitor the publications and public disclosures of the partners to safeguard timely distribution of knowledge to the scientific community with protection of IP rights. To ensure quality control WP1 and WP9 will establish a Publications Plan to be used for the duration of the project, which will include provisions for quality control and methods to ensure adherence to rules for acknowledging the EC funding.

Further details on dissemination and communication of results can be found in the separate dissemination and communication plan and the grant agreement. There are also details on IP management and exploitation of results in the grant agreement, data management plan, consortium agreement and the Implementation plan prepared by the Innovation Management Board.

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## 16. APPENDICES

### 16.1 Risk Assessment and Reporting

In the ECoWeB 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

In response to recommendations from our ethical review boards we have now added a pre-screening section to our assessment to allow those with experience of, or symptoms of depression to access help pages linking to sources of support as soon as possible. Participants are given the following paragraph and options:

This study aims to understand emotions and to promote emotional well-being and prevent future mental ill health in young people who are currently well.

If you are currently struggling with depression, traumatic experiences, Bipolar Disorder, psychosis, suicidal thoughts or have had clinical depression in the past then the trial would not be right for you as specialist help would be the best option for you. Find out more about these difficulties and how we define them below:

If these issues are affecting you now then we would urge you to reach out to family, friends or your family doctor/general practitioner. Find out relevant helpful information and sources of support below:

Click the relevant button below to proceed:

- Find out more about these disorders and how we define them
- Find helpful information and sources of support for current problems
- **I do not have any of these difficulties and I would like to take part in the ECoWeB trial**
- I do not want to take part

The first 2 options are linked to the following help pages which have been adapted from the feedback pages listed below from page 113.

Page 1- Find out more about these disorders and how we define them:

#### **Information on Clinical Depression, Bipolar Disorder and Psychosis**

We have provided you with some information on these disorders so you can identify if any of these have been a problem for you. At the bottom of the page is a continue button to allow you to return to the previous menu where you can choose to view sources of help and advice.

#### **What do we mean by Clinical Depression?**

When we talk about clinical depression, we don't mean just feeling a bit sad, down or depressed for a few hours or day. Clinical depression is not just the low mood that we all experience some of time, but rather a serious illness.



To be diagnosed as having “clinical” depression (typically called major depression), you need to experience **at least 5 of the following symptoms** and they each need to last **all day every day continuously for at least two weeks**, and to interfere with your ability to work or study and your relationships with family and friends:

- Depressed mood (feeling unhappy and down) most of the day, nearly every day
- Losing interest in all activities and not enjoying anything
- Finding it hard to make decisions or to concentrate
- Feeling tired all day every day
- Feeling restless/agitated or conversely really slowed down
- A big loss (or gain) in appetite and/or weight
- Sleeping more or less than normal
- Feeling useless, inadequate and hopeless
- Repeated thinking about death, suicide or harming yourself

If you have ever experienced at least 5 of these symptoms most of the day every day for at least 2 weeks, then you are not suitable for the ECoWeB study because it is focused on prevention and health promotion.

**If you are currently experiencing at least 5 of these symptoms most of the day every day for at least 2 weeks then you should seek help from your GP or family doctor.**

For more info about depression see: [www.mind.org.uk/information-support/types-of-mental-health-problems/depression](http://www.mind.org.uk/information-support/types-of-mental-health-problems/depression) and [www.nhs.uk/conditions/clinical-depression](http://www.nhs.uk/conditions/clinical-depression)

You can also find out more information on our website help pages at [www.mymoodcoach.com](http://www.mymoodcoach.com)

### **What do we mean by bipolar disorder?**

Bipolar disorder involves your moods swinging from one extreme to another. It was previously called manic depression. It typically involves periods of clinical depression and periods of feeling very high, positive or agitated and overactive, known as mania.

Mania is not just feeling good or positive. To be diagnosed as “mania”, at least 3 of the following symptoms need to be present nearly every day for at least one week, and to interfere with your ability to work or study and your relationships with family and friends:

- Inflated sense of self-esteem or grandiose thoughts (feeling very self-important)
- Having what seem like great new ideas and very (over) ambitious plans
- Feeling very happy, elated or overjoyed (a prolonged high feeling)
- Talking more and talking very quickly
- Decreased need for sleep
- Being easily distracted
- Feeling quite agitated and finding it hard to stay still
- Being much more active than normal
- Doing things that could have painful consequences and that others see as risky or harmful, often out of character, e.g., spending sprees, gambling,
- Bipolar disorder would normally only be diagnosed after seeing a specialist doctor such as a psychiatrist.

**If you have ever experienced mania, then your GP or a mental health professional would be the best person to contact regarding help and support. As the ECoWeB study is focused on preventing mental health difficulties rather than treating existing problems, taking part in the trial would not be right for you.**

For more information, see [www.nhs.uk/conditions/bipolar-disorder](http://www.nhs.uk/conditions/bipolar-disorder)

### **What do we mean by psychosis?**

Psychosis is a mental health problem where people perceive or interpret things differently from those around them. It typically involves delusions and/or hallucinations.

A hallucination is where a person hears, sees or feels, tastes and smells things that do not exist outside their mind but that feel very real to them. The most common form is hearing voices, where the person experiences the sound of voices talking when the speaker is not present.

A delusion is holding a strong belief that is not shared by others, e.g. someone believing that there is a conspiracy to harm them.

**You should see a GP / family doctor immediately if you are experiencing the symptoms of psychosis. As the ECoWeB study is focused on preventing mental health difficulties rather than treating existing problems taking part in the trial would not be right for you.**

For more information - [www.nhs.uk/conditions/psychosis](http://www.nhs.uk/conditions/psychosis)

If you click continue this will take you back to the previous menu. You can find a link to sources of help there or on our web page at [www.mymoodcoach.com](http://www.mymoodcoach.com).

Page 2: Find helpful information and sources of support for current problems

## **MENTAL HEALTH HELP**

### **How to access your GP:**

If you are struggling with poor mental health and it is interfering with your daily life, then the first thing to do is to seek help from your family doctor or GP. 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](https://111.nhs.uk) 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. Because healthcare arrangements may change because of COVID-19, please check your GP practice's website and the NHS website at <https://www.nhs.uk/conditions/coronavirus-covid-19/> If you have difficulties accessing your GP due to COVID-19 then do consider trying the helpful [websites](#) and [helplines](#) below.

### **Help if you are feeling suicidal:**

**If you have been thinking about suicide or about hurting yourself, we strongly recommend that you contact your general practitioner or family doctor RIGHT AWAY for advice and tell them how you are feeling.**



Having thoughts of suicide is nothing to be ashamed of and we encourage you to tell someone how you are feeling. There are lots of people available to listen and help you. Talk to your trusted person, call your GP, ring [111](tel:111), or the Samaritans on [116 123](tel:116123), or any of the other helplines below.

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.

If you're feeling like you need to harm yourself, take steps to keep yourself safe:

- 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 may be 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 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.
- 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.
- It can also be helpful to think about your faith, loved ones, family and pets.

The Samaritans offer a confidential service so you can talk about your feelings

Call: [116 123](tel:116123) (available 24-7 free to call) Email: [jo@samaritans.org](mailto:jo@samaritans.org) (response time 24hrs)

### Helpful Self-Care

There are several things that you can do to help look after yourself.

- **Seek help:** Talk to your doctor or another health professional or a school/university counsellor to get the best help.
- **Talk to someone:** It is a good idea to not keep problems and upsets to yourself – talking to someone close to you, and telling them how you feel, sharing your concerns, and asking for help can help to come to terms with upsetting events.

- **Do something:** It is a good idea to be active. Being physically active can improve mood, and exercise can itself have antidepressant effects. Getting outside and seeing the natural world can be beneficial. As best you can, try and do things that you enjoy and value. It is easy to stop doing positive things when depressed, so it is a good idea to build these up. Try and build things up in small steps.
- **Look after yourself physically:** As best you can, try to eat regularly and healthily. When feeling unwell, it is easy to either skip meals or eat badly, which only worsens how you feel. Similarly, be careful with alcohol and drugs like cannabis – many people use alcohol and drugs to relax and numb their distress, but they actually make moods worse. Try and have a regular sleep routine – going to bed at the same time and getting up at the same time.
- **Connect with others:** When feeling down, it is easy to withdraw from others. Mixing with others and getting involved with friends and family can help your mood. Helping other people can also improve your mood.
- **Tackle problems:** If there is an underlying difficulty, trying to solve this problem might help. Write down the problem, all the different things you could do to tackle it and then try the option that is most likely to help.
- **Stay hopeful:** Whilst it may not feel like it, you will eventually feel better – most people recover and there are helpful treatments.

#### Helpful Websites:

- Students against depression is a website by students, for students offering information [www.studentsagainstdepression.org](http://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. [www.youngminds.org.uk/find-help](http://www.youngminds.org.uk/find-help)
- Mind the Mental Health Charity provide information, advice, and support to empower anyone experiencing a mental health problem and tips for everyday living. [www.mind.org.uk](http://www.mind.org.uk)
- 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 [www.rethink.org/living-with-mental-illness/young-people](http://www.rethink.org/living-with-mental-illness/young-people)
- For bipolar disorder: [www.mind.org.uk/information-support/types-of-mental-health-problems/bipolar-disorder](http://www.mind.org.uk/information-support/types-of-mental-health-problems/bipolar-disorder)
- For psychosis: [www.mind.org.uk/information-support/types-of-mental-health-problems/psychosis](http://www.mind.org.uk/information-support/types-of-mental-health-problems/psychosis)
- For schizophrenia: [www.mind.org.uk/information-support/types-of-mental-health-problems/schizophrenia](http://www.mind.org.uk/information-support/types-of-mental-health-problems/schizophrenia)

- **Bipolar UK:** National charity dedicated to supporting individuals with bipolar, their families and carers. Their website has information leaflets and links to support, including a peer support line: [www.bipolaruk.org.uk](http://www.bipolaruk.org.uk)

### Useful helplines:

- **The Samaritans** offer a confidential service so you can talk about your feelings. Call: [116 123](tel:116123) (available 24-7 free to call). Email: [jo@samaritans.org](mailto:jo@samaritans.org) (response time 24hrs)
- **Papyrus** offer national support to young people up to age 35 who are feeling suicidal. Available Mon-Fri 10:00am-5:00pm & 7:00pm-10:00pm and Weekends 2:00pm-5:00pm. Call: [0800 068 4141](tel:08000684141) Text: [07786209697](tel:07786209697) Email: [pat@papyrus-uk.org](mailto:pat@papyrus-uk.org)
- **Maytree** are a registered charity supporting people in suicidal crisis. Call: [020 7263 7070](tel:02072637070)(Available 24-7). Email: [maytree@maytree.org.uk](mailto:maytree@maytree.org.uk)
- **Young Minds Crisis Messenger** provides **crisis** support across the UK. Text: [YM to 85258](tel:085258) (Available 24/7 Texts are free from EE, O2, Vodafone, 3, Virgin Mobile, BT Mobile, GiffGaff, Tesco Mobile and Telecom Plus.)
- **CALM** offers support to young **men** in the UK who are down or in a crisis. Call: [0800 58 58 58](tel:0800585858) (Available Daily 5:00pm – midnight)
- **ChildLine** offer confidential calls, emails, or online chats for anyone under 19 for support with any problem big or small. Call: [0800 1111](tel:08001111) (Available 24-7 free). You can also sign up for a childline account on the website to be able to message a counsellor anytime without using your email address and can Chat 1:1 with an online advisor

If you click continue this will take you back to the previous menu. You can find a link to sources of help there or on our web page at [www.mymoodcoach.com](http://www.mymoodcoach.com).

We have also added a new page to the website which details where to find more information related to COVID-19. This can be found at <https://www.mymoodcoach.com/covid-19>.

### 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 elevated symptomatology risk will be logged by the electronic system and the relevant research officer for each trial site informed.

We note that the nature of the high level of confidentiality on the app means that we do not 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 for ECoWeB is direct information disclosure to the participant of a potential clinical issue with appropriate advice and signposting. Transmission of the collected information to the GP will not be routinely possible, and requesting this information a priori would negate the ethical and recruitment benefits of pseudo-anonymity and confidentiality for participants. Nonetheless, when we

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alert a young person 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. Hence we provide them to pages with links to sources of help.

Where legally required or recommended by good clinical practice guidelines in Germany and Belgium, for those under the age of majority (16 or 17 years old) the young person’s parents or legal guardians will be informed and provided information about where they can seek support if information is provided that indicates a possible clinical presentation or significantly elevated risk for poor mental health.

### **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.

In this trial no medical care is provided regardless of the level of risk presented. This is because we are an international promotion/prevention trial delivering a self-help through an App and so will not have 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 2 ways that that a recruit or participant could indicate risk to the research team either via the assessment website (Qualtrics) at baseline, or on a follow-up assessment, or in direct contact with a trial researcher by phone, text or email.

#### Screening Website at Baseline

A recruit may indicate risk on the screening website in the screening phase of the baseline 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)*

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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 be excluded from the trial and would be automatically presented with the following risk page (exampled for UK):



**“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 ECoWeB 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 ECoWeB app 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 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](mailto: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](http://www.samaritans.org), Email: [jo@samaritans.org](mailto:jo@samaritans.org)
- **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 6pm-11 pm
- **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](mailto: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](http://www.thecalmzone.net)
- **ChildLine**, Freephone 24h helpline: **0800 1111** If you're under 19 you can confidentially call, email, or chat online about any problem big or small, [www.childline.org.uk](http://www.childline.org.uk). You can sign up for a [childline account](#) on the website to be able to message a counsellor anytime without using your email address and can Chat 1:1 with an [online advisor](#)
- **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](http://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 ECoWeB team, you can contact us by submitting the form below to send an email to the research team.

We note that the ECoWeB researchers 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 ECoWeB 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) Assessment Website at Follow-up (1 month, 3 month, 12 months)**

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?*



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*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 (for UK):

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## Screening Website Automated Risk Message at Follow up:



**“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.

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](mailto: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](http://www.samaritans.org), Email: [jo@samaritans.org](mailto:jo@samaritans.org)
- **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 6pm-11pm
- **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](mailto: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](http://www.thecalmzone.net)
- **ChildLine**, Freephone 24h helpline: **0800 1111** If you're under 19 you can confidentially call, email, or chat online about any problem big or small, [www.childline.org.uk](http://www.childline.org.uk). You can sign up for a [childline account](#) on the website to be able to message a counsellor anytime without using your email address and can Chat 1:1 with an [online advisor](#)
- **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](http://www.themix.org.uk)

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

We note that the ECoWeB researchers we 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 ECoWeB 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 chief investigator and logged by the trial manager, and passed on to the relevant site. 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.

Participants excluded at baseline with current depression (without risk)

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If a participant reports current or past history of depression at baseline, but then does not report current risk then they are ineligible for the ECoWeB cohort and trial on the study funding conditions and remit.

The screening website will automatically provide them with the following information if they meet criteria for current depression:

### Screening Website Automated message for depression



**“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.**

The ECoWeB study has been funded to improve wellbeing and prevent poor mental health in young adults that have had no problems until now. Unfortunately, the current study is not suitable for anyone who is currently depressed. Thank you for your interest

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:

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](mailto: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](http://www.samaritans.org), Email: [jo@samaritans.org](mailto:jo@samaritans.org)
- **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 6pm-11pm
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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.**

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**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:**

#### **Follow-up Website Automated message for depression**



**“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.

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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/>

- **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.nrw.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:

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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](http://www.samaritans.org), Email: [jo@samaritans.org](mailto:jo@samaritans.org)
- **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 6pm-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](http://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.**



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## Participants excluded at baseline with past history of depression (without risk)

The screening website will automatically provide them with the following information if they meet criteria for past history of depression:



**“Your responses to these questions suggest that at some point in your life your overall mood has been low for at least 2 weeks and has had a negative effect on your life. This suggests that you may have experienced clinical depression in the past.**

The ECoWeB study has been funded to improve wellbeing and prevent poor mental health in young adults that have had no problems until now. Unfortunately, the current study is not suitable for anyone who has a history of depression. Thank you for your interest

If you currently are having problems or if in the future you have 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.

If you are willing for us to contact about potential future studies please indicate your consent to be contacted by completing the form below:

Your Name	<input type="text"/>
Your Address	<input type="text"/>
Your telephone number	<input type="text"/>
I consent to be contacted about future studies <input type="checkbox"/>	

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

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-

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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](mailto: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](http://www.samaritans.org), Email: [jo@samaritans.org](mailto:jo@samaritans.org)
- **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 6pm-11pm
- **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](mailto: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](http://www.thecalmzone.net)
- **ChildLine**, Freephone 24h helpline: **0800 1111** If you're under 19 you can confidentially call, email, or chat online about any problem big or small, [www.childline.org.uk](http://www.childline.org.uk). You can sign up for a [childline account](#) on the website to be able to message a counsellor anytime without using your email address and can Chat 1:1 with an [online advisor](#)
- **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](http://www.themix.org.uk)

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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.**

**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 the ECoWeB study is focused on promoting mental health and preventing poor mental health in the future, rather than treating current difficulties, the current study is not suitable for you at this time. The ECoWeB app 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:

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/#.XGQJIX7SUK>
  - **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>

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- There are a series of NHS self-help guides which can be found here <https://web.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](mailto: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](http://www.samaritans.org), Email: [jo@samaritans.org](mailto:jo@samaritans.org)
- **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 6pm-11pm
- **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](mailto: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](http://www.thecalmzone.net)
- **ChildLine**, Freephone 24h helpline: **0800 1111** If you're under 19 you can confidentially call, email, or chat online about any problem big or small, [www.childline.org.uk](http://www.childline.org.uk). You can sign up for a [childline account](#) on the website to be able to message a counsellor anytime without using your email address and can Chat 1:1 with an [online advisor](#)
- **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](http://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.**

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 the ECoWeB study is focused on promoting mental health and preventing poor mental health in the future, rather than treating current difficulties, and we are testing the effect of the self-help apps, currently receiving psychological therapy means that this study is not suitable for you at this time. Taking part in the EcoWeb study may not be in your best interests at this time as it's important for you to focus fully on your therapy right so that you get the most out of it. 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:

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

- **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/>
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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>

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- 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](http://www.samaritans.org), Email: [jo@samaritans.org](mailto:jo@samaritans.org)
- **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 6pm-11pm
- **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](mailto: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](http://www.thecalmzone.net)
- **ChildLine**, Freephone 24h helpline: **0800 1111** If you're under 19 you can confidentially call, email, or chat online about any problem big or small, [www.childline.org.uk](http://www.childline.org.uk). You can sign up for a [childline account](#) on the website to be able to message a counsellor anytime without using your email address and can Chat 1:1 with an [online advisor](#)
- **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](http://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**.



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## ECoweB Risk Assessment and Reporting SOP

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.

We note that guidance on depression and suicide including general advice, signposting for help, websites and telephone lines (as for webpages noted above) are also provided within the help section within all versions of the App.

### 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 ECoWeb 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 killing yourself?" 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 or kill yourself? YES OR NO

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### PLANS

1 Do you know how you would kill yourself?

Yes / No

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

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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 kill yourself? 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

5. **PREVENTION** Is there anything stopping you killing or harming yourself at the moment? Yes / No

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

6. Do you feel that there is any immediate danger that you will harm or kill yourself? 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) whilst maintaining conversation with participant.

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### 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 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 or kill yourself?

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 killing yourself. 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 killing 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**,

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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 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 ECoWeB risk assessment and reporting SOP including responding to participant 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:**

1. Document action taken on the risk log and a risk report form (see below).
2. Fax or send letter to GP documenting information gathered and action taken.
3. Seek / offer supervision around support and debriefing as appropriate.

**"Risk Report Form**

Participant Trial Number

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

Researcher / assessor: \_\_\_\_\_ Signed: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

Supervisor: \_\_\_\_\_ Signed: \_\_\_\_\_ Date: \_\_\_\_/\_\_\_\_/\_\_\_\_

**SAE Reporting Form**

**Adverse Events Reporting Form**

## REPORT OF SERIOUS ADVERSE EVENT (SAE)

(For all studies except clinical trials of investigational medicinal products)

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 7 days of the CI becoming aware of the event. Any adverse events should also be notified to the Independent Chair of the Trial Steering Committee. For further guidance see: <http://www.nres.npsa.nhs.uk/applicants/review/after/safety.htm>.

### 1. Details of Site Principal Investigator

Name:	
Address:	
Telephone:	
Email:	
Fax:	

### 2. Details of study

Full title of study:	
Name of main REC:	
Main REC reference number:	
Research sponsor:	
Sponsor's reference for this report: (if applicable)	

### 3. Type of event

Please categorise this event, ticking all appropriate options (common exemplars of adverse events relevant to a mental health trial are added in parentheses):

Death (homicide, suicide, accident, illness, etc.) <input type="checkbox"/>	Life threatening (suicide attempt, serious assault, self- harm) <input type="checkbox"/>	Hospitalisation or prolongation of existing hospitalization <input type="checkbox"/>
Persistent or significant disability or incapacity (include development of problematic substance/ alcohol abuse; onset of new Axis I disorder) <input type="checkbox"/>	Congenital anomaly or birth defect (n/a) <input type="checkbox"/>	Other (potentially dependent life events, e.g., job loss divorce) <input type="checkbox"/>

### 4. Circumstances of event

Date of SAE:	
Location:	

Describe the circumstances of the event:  <i>(Attach copy of detailed report if necessary)</i>	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

### 5. Declaration

Signature of Chief Investigator:	
Print name:	
Date of submission:	

### 6. Acknowledgement of receipt by main REC (please insert name):

The [ ] Research Ethics Committee acknowledges receipt of the above.

Signed:	
Name:	
Position on REC:	

*Signed original to be sent back to Chief Investigator (or other person submitting report) Copy to be kept for information by main REC*



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**ECoWeB draft G risk letter (for participants in trial)**

Sir Henry Wellcome Building for Mood Disorders Research,  
School of Psychology  
College of Life and Environmental Sciences,  
University of Exeter

EX4 4QG.

GP practice Address

Dear Dr XXX

**Re: XXX, DOB XXX**

I am writing to inform you that XX has chosen to participate in the ECoWeB Cohort which investigates emotional skills and wellbeing in young people over a one year prospective study, and which includes the opportunity to be offered to use different versions of a mobile phone self-help app to improve well-being and prevent poor mental health. The ECoWeB trial is funded by the European Commission and is being conducted by the Mood Disorders Centre, University of Exeter and Universities in Spain, Belgium and Germany.

Participants who respond to online advertising are being offered the opportunity to be screened for inclusion in the study. At the time of screening your patient XX did not report symptoms potentially consistent with a current or past diagnosis of major depression, and thus was eligible for the cohort study. During an email/telephone discussion with the research team/ at their 1/3/12 month follow up XX informed us that he/she has had thoughts of death and suicide in the past 2 weeks. She also reported that .....

X is currently presenting with symptoms consistent with a potential diagnosis of X Disorder.

Because of the thoughts that X is currently experiencing, I have advised her to make an appointment with you as soon as possible and he/she has been emailed with/ provided with advice on staying well through our screening website. In view of this finding, it is our practice to keep the patient's GP informed of any potential risk disclosed. The clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan.

Yours sincerely,

Dr X ECoWeB Trial Manager

**Supervised by Prof Ed Watkins, Professor of Clinical Psychology**

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**ECoWeB draft GP risk letter (for non-risky participants who are excluded from the trial; i.e., those with diagnosis of current depression or bipolar disorder or psychosis)**

Sir Henry Wellcome Building for Mood Disorders Research,  
School of Psychology  
College of Life and Environmental Sciences,  
University of Exeter  
EX4 4QG.

GP practice Address

Dear Dr XXX

**Re: XXX, DOB XXX**

I am writing to inform you that XX recently applied to participate in the ECoWeB Cohort which investigates emotional skills and wellbeing in young people over a one year prospective study, and which includes the opportunity to be offered to use different versions of a mobile phone self-help app to improve well-being and prevent poor mental health. The ECoWeB trial is funded by the European Commission and is being conducted by the Mood Disorders Centre, University of Exeter and Universities in Spain, Belgium and Germany.

Participants who respond to online advertising are being offered the opportunity to be screened for inclusion in the study. At the time of screening your patient XX reported symptoms which are consistent with a diagnosis of current depression/ prior diagnoses and/or treatment for bipolar disorder/psychosis, which means he/she is not eligible for this cohort study

X is currently presenting with symptoms consistent with X Disorder. Because of the symptoms X is currently experiencing, I have advised him/her to make an appointment with you as soon as possible. He/she has also been provided with information about websites and helplines for further information and support.

It is our practice to keep the patient's GP informed of any potential risk disclosed. The clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan.

Yours sincerely,

Dr X

ECoWeB Trial Manager

**Supervised by Prof Ed Watkins, Professor of Clinical Psychology**

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## **16.2 Trial management / responsibilities**

### **Trial Management**

A dedicated trial manager will assist day-to-day management of the project, coordinate across sites and institutions, and will be responsible for effective communication and monitoring progress. The trial will be managed by a core research team who will meet weekly (lead of WP7 and trial manager). There will be a Cohort Trial Senior Management group, consisting of the lead researcher at each recruitment site 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](http://www.controlledtrials.com) 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.

#### **16.2.1 Patient registration/randomisation procedure**

At the point of randomisation participants will be automatically registered on to the trial using the trial screening website. Randomisation is after the online consent, the screening process and after the online baseline assessment. The consent forms on the screening website are available separately to this protocol. 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 baseline 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.

#### **16.2.2 Data management**

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

All data collected within the framework of the study will be pseudo-anonymised and securely stored at a central location under the responsibility of the study sponsor (UNEXE). The conduct of the project will comply with the Directive 95/46/EC of the European Parliament and of the Council of Europe dated 24th October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, and with the new regulation Regulation (EU) 2016/679 ([http://ec.europa.eu/justice/dataprotection/reform/files/regulation\\_oj\\_en.pdf](http://ec.europa.eu/justice/dataprotection/reform/files/regulation_oj_en.pdf)) that will replace it and with 1997/66/CE on the handling of personal information and Directive 2002/58/CE (on the same subject). It will comply with regulations transposing this directive at the national level (e.g. Data Protection Act (DPA) number g0027154 in the UK; Bundesdatenschutzgesetz (BDSG) in Germany; "Privacywet" KB 13/02/2001 & KB 17/12/2003 in Belgium).

#### **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

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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. Monsenso hosts and operates its solution on encrypted servers within the EU. The system complies with the EU 2000/58/EC & 2002/58/EC Directive on privacy and electronic communications and the EU Directives 95/46/EC and with the superseding directive 2016/679 GDPR (and Danish Act on Processing of Personal Data implementing EU Directive 95/46/EC). In terms of the Directive 95/46/EC, Monsenso is to be considered a Data Processor, as are the recruitment sites in ECoWeB, and University of Exeter as sponsor will be considered Data Controller. Data Processing agreements between Monsenso and sites and the data controller will be made, stipulating in what manner Monsenso should process data for the purpose of the ECoWeB project.

**Database infrastructure:** The ECoWeB project will build 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 trials, 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 for the trial will be produced as a deliverable at month 16 for all collected data (demographic, behavioural data). 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. Data types will include Volunteer data: Demographics, information provided by participants on questionnaires and on EC assessment instruments.

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Data exploitation: All information will have a digital format that will be handled in accordance with European and 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 ECoWeB 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.

#### **16.2.5 Data protection/confidentiality**

A common privacy and data protection policy has been drafted. This is so that participants will not need to re-read new policies from moving from screener to App to Audeering website when common GDPR standards will apply. For this sample of young adults aged 16-22, it was also important that the data protection policy should be in an easily readable format avoiding legalise. The trial data protection and privacy policy can be found below:

#### **16.2.6 Trial documentation and archiving**

The materials for the trial will be submitted with this study protocol.

### **16.3 Authorisation of participating sites**

Each site will be authorised after ethical approval has been given by the relevant ethics committee for that site and a data transfer agreement is in place between the site and the UNEXE data controller. Site visits (including remote checks) will be conducted by the trial manager to check that sites are adequately staffed, staff researchers have access to a clinical adviser, and that site staff are familiar with the standard operating procedures, risk assessment procedures and that GCP and GDRP standards will be followed.

#### **16.3.1 Required documentation**

Before recruitment can begin at sites, staff CV's and evidence of good clinical practice and GDPR training will be collected. Each site will be provided with copies of the standard operating procedures for the trial. Each site will create a resource of online links and local and national services for those indicating that they have current depression, suicide risk, mania and psychosis. These links will be checked before the trial starts and at monthly intervals during recruitment to ensure that these details are kept up to date.

#### **16.3.3 Principal Investigator responsibilities**

There will be legal data transfer agreements between the UNEXE and the site Universities in Gent, Valencia and Munich and MSS and AUD. Each site is also a grant holder rather than just a site so has committed to uphold the standards outlined in the EU document and in the protocol.

## 16.4 Schedule of Procedures

**Table 16 The Schedule of Procedures**

Procedures	Screening	Baseline (at same time as screening)	1 month Follow Up	3 month follow up	12 month follow up
Informed consent	Yes	Yes	Yes	Yes	Yes
Further Demographics	DOB Gender	Occupation Education level	Occupation DOB	Occupation DOB	Occupation DOB
Mental Health History	Yes	No	No	No	No
Current Physical conditions	No	Yes	No	Yes	Yes
Current medications	No	Yes	No	Yes	Yes
Eligibility assessment	Yes	No	No	No	No
Randomisation	No	Yes	No	No	No
Access to intervention	No	No	Yes	Yes	Yes
Compliance with intervention	N/A	N/A	No*	No	No
Assessment of wellbeing and depression	Y	N	Y	Y	Y
Assessment of emotional competence	N	Y	Y	Y	Y
Assessment of current functioning	N	Y	Y	Y	Y
Assessment of service use	N	Y	N	Y	Y
Adverse event assessments	N	N	Y	Y	Y

\*There are App notifications to the ppt to aid compliance and there is summary reporting of compliance, but no specific check at follow up as this would break blind

## 16.5 Safety Reporting Flow Chart

Safety Flow Chart Version 1

