



## The ABC-UK Randomised Controlled Trial for Young Adults with Depression Symptoms (ABC-UK RCT)

### Trial Identifiers

ISRCTN:	(plan to register on <a href="http://www.isrctn.com/">http://www.isrctn.com/</a> )		
Ethical approval:	Ethics reference number: 14646-19095		
Funding	This trial is funded by the NIHR Bath Mental Health Research Group (award number: NIHR207583)		
Sponsor	This trial is sponsored by the University of Bath		
Protocol Version Number:	1.2	Date:	08.04.2026

### Contact details

#### Chief Investigators (CI)

Name:	Dr Jeffrey Lambert
Address:	Department of Psychology, University of Bath, Claverton Down, Bath BA2 7AY
Telephone:	01225 384536
Email:	<a href="mailto:jl2426@bath.ac.uk">jl2426@bath.ac.uk</a>

Name:	Professor Maria Loades
-------	------------------------

Address:	Department of Psychology, University of Bath, Claverton Down, Bath BA2 7AY
Telephone:	01225 385249
Email:	<a href="mailto:m.e.loades@bath.ac.uk">m.e.loades@bath.ac.uk</a>

**Co-Investigator(s), University of Bath**

Name	Position/Role	Email
Dr Atiyya Nisar	Trial Manager	<a href="mailto:an2408@bath.ac.uk">an2408@bath.ac.uk</a>
Professor Ailsa Russell	Professor of Clinical Psychology	<a href="mailto:A.J.Russell@bath.ac.uk">A.J.Russell@bath.ac.uk</a>

**Co-Investigator(s), Bristol Trials Centre staff**

Name	Position/Role	Email
Dr Jodi Taylor	Director of Operations, Bristol Trials Centre	<a href="mailto:J.Taylor@bristol.ac.uk">J.Taylor@bristol.ac.uk</a>
Dr Katie Pike	Senior Statistician	<a href="mailto:Katie.Pike@bristol.ac.uk">Katie.Pike@bristol.ac.uk</a>
Dr Jo Worthington	Trial Methodologist	<a href="mailto:jo.worthington@bristol.ac.uk">jo.worthington@bristol.ac.uk</a>
Dr Joanna Thorn	Health Economist	<a href="mailto:Joanna.Thorn@bristol.ac.uk">Joanna.Thorn@bristol.ac.uk</a>

**Sponsor**

Name	Address	Email
University of Bath	University of Bath Claverton Down BA2 7AY	<a href="mailto:research-ethics@bath.ac.uk">research-ethics@bath.ac.uk</a>

**Signature page**

Chief Investigator Agreement

The study as detailed within this research protocol will be conducted in accordance with the principles of Good Clinical Practice, the UK Policy Framework for Health and Social Care Research, and the Declaration of Helsinki and any other applicable regulations. I delegate responsibility for the statistical analysis and oversight to a qualified statistician (see declaration below).

Co-Chief Investigator name: Dr Jeffrey Lambert

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Co -Chief Investigator name: Professor Maria Loades

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Contents

<b>Trial Identifiers</b> .....	1
<b>Contact details</b> .....	1
Chief Investigators (CI).....	1
Co-Investigator(s), University of Bath .....	2
Co-Investigator(s), Bristol Trials Centre staff.....	2
Sponsor .....	2
<b>Signature page</b> .....	3
<b>Glossary of Abbreviations</b> .....	6
<b>Summary and synopsis</b> .....	8
<b>Objectives</b> .....	14
Primary objective.....	14
Secondary objectives .....	14
<b>Study population</b> .....	15
Inclusion criteria .....	15
Exclusion criteria .....	15
<b>Study design</b> .....	16
Assessments .....	16
Baseline measures .....	16
Outcome measures .....	16
Table 1. Schedule of Study Assessments and item count.....	19
Figure 1. CONSORT Flow Diagram.....	21
Table 2. Schedule of Enrolment, Interventions and Assessments .....	22
Intervention: Behavioural Activation SSI (BA-SSI) .....	24
Figure 2. Logic model of the intervention .....	25
Intervention adaptation.....	26
<b>Process evaluation</b> .....	28
<b>Health Economic evaluation</b> .....	29
Objective .....	29
Perspective .....	29
Time Horizon .....	29
Outcomes measured .....	29

Cost Identification and Measurement .....	29
Data analysis .....	30
Implementation: Cost effectiveness of different recruitment strategies .....	30
<b>Data Management</b> .....	30
Confidentiality.....	31
Record retention and archiving .....	31
Assessment and management of risk.....	31
Monitoring .....	32
Monitoring of study by Sponsor.....	32
Monitoring of study by study team.....	32
Protocol compliance .....	33
Safety Recording and Reporting.....	33
Definitions .....	33
Adverse Event .....	33
Adverse Reaction .....	33
Serious Adverse Event .....	33
Suspected Serious Adverse Reaction .....	34
Suspected Unexpected Serious Adverse Reaction.....	34
Reporting period.....	34
Reporting overview .....	34
Adverse Events and Serious Adverse Events .....	36
Urgent safety measures .....	37
<b>Statistical considerations</b> .....	37
<b>Sample Size</b> .....	37
Primary analysis.....	38
Secondary analyses .....	38
Sub-group analyses.....	38
Sensitivity Analyses.....	38
Software and Reporting .....	39
<b>Ethics</b> .....	39
Ethical Approval .....	39
Informed Consent Procedures.....	39

<b>Public and patient Involvement</b> .....	39
<b>Roles and Responsibilities</b> .....	40
Trial Committees .....	40
Trial Management Group (TMG) .....	40
Trial Steering Committee (TSC).....	40
Data Monitoring Committee (DMC).....	41
<b>Finance and Funding</b> .....	41
<b>Indemnity</b> .....	41
<b>Dissemination Policy</b> .....	41
<b>Revision History</b> .....	42

## Glossary of Abbreviations

AE	Adverse event
AR	Adverse reaction
CBT	Cognitive Behaviour Therapy
CHERRIES	Checklist for Reporting Results of Internet E-Surveys
CI	Chief Investigator
CONSORT	Consolidated Standards of Reporting Trials
DMHI	Digital mental health intervention
GCP	Good Clinical Practice
LSMH	Lab for Scalable Mental Health
NHS	National Health Service
NIHR	National Institute for Health Research
PBA	Person-based Approach
PHQ	Patient Health Questionnaire
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SSI	Single Session Intervention
SUSAR	Suspected Unexpected Serious Adverse Reactions
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

YAC	Young Adult Consultants
-----	-------------------------

**Summary and synopsis**

Short title	The ABC-UK SSI trial for UK young adults with depression symptoms RCT
Trial Design	Two arm parallel groups randomised hybrid Type 1 effectiveness-implementation RCT
Research sites	<p>The research site is the University of Bath. All research procedures, assessments and the intervention themselves will be on the REDCap and Qualtrics survey platforms. Recruitment will be aimed at the general public through sharing study adverts via community organisations including voluntary and third sector organisations, particularly those offering anonymous/early help, as well as through mass media promotion and limited use of social media. These adverts will signpost and direct potential participants to our codesigned website, <a href="http://www.unlockwellbeing.org.uk">www.unlockwellbeing.org.uk</a> where more information will be presented in an engaging way, together with a link to access the research database where all research activities take place.</p>
Objectives / aims	<p>Primary objective</p> <p>To determine whether the ABC-UK SSI, in addition to enhanced usual care reduces depressive symptoms 1-month post-intervention in young adults in the UK compared to enhanced usual care alone.</p> <p>Secondary objectives</p> <ol style="list-style-type: none"> <li>1. To determine whether the ABC-UK SSI, in addition to enhanced usual care reduces anxiety symptom severity, b) improves functioning and c) increases mental well-being</li> <li>2. To undertake a health economic evaluation to determine the cost-effectiveness of the ABC-UK SSI.</li> <li>3. To complete a process evaluation to establish where young adults are recruited from, and interest, uptake, engagement, completion and experience of the intervention and trial.</li> <li>4. To determine whether any adverse events and/or harms are reported amongst participants who complete the ABC-UK SSI.</li> </ol>
Intervention	ABC-UK Single Session Intervention (SSI); a web-based, self-guided behavioural activation programme delivered via Qualtrics. It provides psychoeducation, values clarification, and guided selection of personalised value-based activities, supported by planning exercises to anticipate obstacles and enhance

	engagement, using brief videos, vignettes, and reflective tasks, including action planning.
Number of participants	264
Inclusion and exclusion criteria	<p>Inclusion criteria:</p> <ul style="list-style-type: none"> <li>- Adolescents aged 19-25</li> <li>- Who live in the UK,</li> <li>- Who report elevated depressive symptoms - score of <math>\geq 2</math> on the Patient Health Questionnaire, 2 item version (PHQ-2),</li> <li>- Are fluent in English,</li> <li>- Have internet access.</li> <li>- Can complete informed consent procedure</li> </ul> <p>Exclusion criteria: Individuals who do not meet prespecified data quality criteria, designed to detect bots (i.e., automated form fillers) and random responders. Those who endorse active suicidal intent/plans to act will also be excluded.</p>
Statistical methodology and analysis (if applicable)	Treatment effects will be evaluated by estimating differences in PHQ-9 scores between groups using a linear mixed-effects model, with adjustment for age, gender, and baseline depression severity. To examine effects among those who adhere to the intervention, a complier average causal effect (CACE) analysis will also be undertaken. Reporting will follow CONSORT recommendations, alongside guidance from the CHERRIES checklist.
Study duration	<p><i>&lt;estimated duration for the main study protocol (i.e. time from receipt of all approvals to the time the last participant has completed all study procedures)&gt;</i></p> <p>(2,y 4m years) including:</p> <ul style="list-style-type: none"> <li>• 12m set-up (April 2025-March 2026)</li> <li>• 6m recruitment (April 2026-September 2026)</li> <li>• 6m last participant last follow-up (by end March 2027)</li> <li>• Data cleaning, analysis and write up (January 2027-July 2027)</li> </ul>

## **Introduction**

Sixty-two percent of mental health disorders develop by age 25 (Solmi et al., 2022), contributing to 45% of the global burden of disease in this age range (Gore et al., 2011). A distinct, but often overlooked group, is young adults aged 18-25 (this is sometimes referred to as “emerging adulthood”). Young adults have unique life experiences and stressors during these years. This phase of becoming independent from their family of origin is a heavily transitional time in various arenas of their life, including managing finances independently for the first time, entering and leaving higher education, and joining the workforce (Loades, 2025; Wood et al., 2021). Additionally, changing economic circumstances and societal norms have delayed the age at which certain milestones are reached. For example, from 2011 to 2021, the average age at which young adults in England and Wales moved out the family home rose from 21 to 24 (Office for National Statistics, 2024). Neuropsychologically, emerging adulthood remains a critical period for the maturation of the prefrontal cortex (Dumontheil, 2016). This region underpins the executive functioning processes which are pivotal for the development of emotional regulation and recognition.

One of the most common mental health disorders in young adults is depression, with an estimate prevalence of 33.6% in university aged students (Li et al., 2022). Depression is characterised by persistent feelings of sadness and a loss of interest or enjoyment in activities (American Psychiatric Association, 2013). Depression symptoms can range in clinical severity, from mild to severe. There is substantial individual and societal impact of young adults’ depressive symptoms, both short term and across the life course. Adverse outcomes include impairments in educational attainment (Bruffaerts, 2018) and interpersonal relationships, recurrence of depressive symptoms in later adulthood, increased need for social support and increased unemployment (Thapar et al., 2020). There are also considerable economic costs associated with depressive symptoms across the lifespan (König et al, 2019). Therefore, providing mental health support for young adults experiencing depressive symptoms is a public health imperative.

## **Access to Mental Health Provision**

Despite this scale and burden, the mental health needs of young adults are largely still unmet (Colizzi, 2020). Young adults face a range of barriers when seeking and engaging with mental health support. This includes waiting lists for mental health services of up to 18 weeks on average in the UK, which can further exacerbate existing mental health issues and reduce motivation to seek support (Punton et al., 2022). For young people accessing child and adolescent mental health services who are newly entering young adulthood, the transition for child to adult mental health services is reported to be poorly planned and executed (Singh et al, 2010). Stigma around discussing mental health is also frequently cited by young adults as a barrier to accessing support (Gulliver et al, 2010), and this is a particular concern for individuals from ethnic minority backgrounds, who are disproportionately impacted by mental health stigma (Eylem et al., 2020). Additionally, there is a need for mental health support which is bespoke to the developmental stage and contextual needs of this age group. Preliminary qualitative work from our group suggests young adults view their

support needs as distinct from those of adolescents and adults, reinforcing the need for age-specific provision (Jenkins et al., submitted).

Evidence-based psychotherapies for treating depression such as Cognitive-Behaviour Therapy (CBT), Acceptance and Commitment Therapy (ACT) and interpersonal psychotherapy have been established to effectively reduce depressive symptoms for young adults (Riddle et al., 2024). However, these treatments are all traditionally delivered by trained therapists, which can be a significant barrier to making treatment accessible to all. The mental health workforce in the NHS is insufficient to meet the demand for support, leading to limited service capacity and long wait times (British Medical Association, 2025).

Given the prevalence of mental health difficulties in young adults, there is a need to identify scalable and accessible alternatives to therapist delivered services.

## **Rationale**

Mental health treatment can be made scalable and accessible through the use of digital technology. Digital mental health interventions (DMHIs) use digital platforms to provide prevention or treatment of mental health issues. DMHIs can be fully self-guided, or facilitated by human supporters, including trained therapists. There are many types of DMHIs, including smartphone apps, virtual reality (VR), structured web-based programs (Hollis, Loades & Hall, 2025). There is good evidence for the effectiveness of DMHIs when used with young adults. A systematic review of the impact of DMHIs for college students by Taylor et al. (2024) reviewed 95 relevant studies, 72% of which were randomised controlled trials (RCTs). They found that over 80% of studies reported full or partial improvements in the primary outcome. For the 23 studies where depression symptoms and/or diagnoses was the primary outcome measure, 83% of participants showed reduction in depression symptoms, highlighting the potential of DMHIs in addressing mental health issues in this population.

DMHIs are most scalable when they are offered as self-guided help tools which are not reliant on therapist input. However, adherence is a significant barrier - they are often not fully completed or are only accessed once, despite being designed for repeated use (Fleming et al., 2018; Linardon et al., 2024). Therefore, there is a need to identify DMHIs where repeated use is not a pre-requisite to achieve meaningful improvements in mental health. A promising approach to achieving tangible mental health benefits from brief engagement with DMHIs is the use of Single-Session Interventions (SSIs). SSIs are “structured programs that intentionally involve only one visit or encounter with a clinic, provider, or program” (Schleider et al., 2020). An umbrella review of systematic reviews and meta-analyses by Schleider et al., (2025) identified twenty-four systematic reviews of SSIs, which reported the findings of 415 trials. Of the twenty-four reviews, twenty reported positive impact of the SSIs, across a range of mental health outcomes, including depression and anxiety. Additionally, across the twelve reviews that meta-analysed effectiveness compared to controls, small but positive impact was reported, across age groups and mental health outcomes.

The acceptability and impact of digital SSIs for young people and young adults have been established through RCTs. A meta-analytic review of self-help SSIs for young people’s mental health by Ball et al.

(2024) synthesised findings from 22 randomised controlled trials ( $n = 5,452$ ; participants aged up to 25 years). Across the 19 studies included in the quantitative synthesis, SSIs were associated with small but significant reductions in both anxiety (Hedges'  $g = -0.22$ ) and depression symptoms ( $g = -0.12$ ), although there was considerable heterogeneity and a wide prediction interval.

There is nascent research exploring the utility of SSIs for UK young adult populations. An RCT of COMET-GB, an online self-help SSI which incorporates gratitude, self-compassion, behavioural activation and cognitive restructuring, was conducted with 468 university students in the UK (Lambert et al., 2025). Compared to controls, the COMET-GB group showed significant improvements in depression severity, perceived stress and subjective well-being at 2-week follow-up. Participants generally found the intervention to be acceptable, appropriate and helpful, but reported that the intervention was too lengthy. These findings indicate that digital SSIs can be an effective scalable approach to addressing mental health difficulties for young adults in the UK.

### **The Action Brings Change SSI (a.k.a. Project ABC)**

Behavioural activation (BA) is a time-limited structured talking therapy rooted in CBT, which seeks to address depression by decreasing avoidance behaviour and increasing engagement in activities which improve mood and provide positive reinforcement (Jacobson, Martell and Dimidjian, 2001). BA has been shown to be effective in reducing depressive symptoms in both young people and adults. A meta-analysis of studies of BA (delivered in-person, online and via telephone) with young people identified a small effect of BA (Hedges  $g = 0.24$ ) in reducing depressive symptoms in comparison to waitlist controls, other therapies and usual care (Tindall et al., 2024). In adults, a Cochrane review of 53 RCTs ( $n = 5495$ ) of BA for treatment of depression identified that BA was equally as effective as CBT, and superior to humanistic therapy and medication, in addressing depressive symptoms (Uphoff et al., 2020).

Due to the brief, structured nature of BA, this has resulted in it being adapted for delivery in a digital format. A systematic review and meta-analysis by Jie et al., (2025) assessed the effectiveness of digital BA interventions for depression and anxiety. They identified 17 RCTs, 12 of which were included in the meta-analysis. Digital BA interventions were found to be associated with significant decreases in depressive symptoms at 2-, 3- and 6-months post-intervention, indicating that BA can be effectively adapted for delivery in a digital format.

Distilling BA into an online self-help SSI may be beneficial as it could eliminate the need for sustained effort or repeated engagement, which are established barriers in DMHIs. A BA-based SSI, called Project Action Brings Change (ABC), has been developed by the Lab for Scalable Mental Health in the USA. It has been evaluated as part of a three-arm RCT by Schleider et al., (2022), comparing the BA-SSI with a growth mindset (GM) SSI and active control. Participants were U.S adolescents aged 13-16 ( $n = 2452$ ). At three-month follow-up, both the BA and GM were associated with small but significant reductions in depressive symptoms (Cohens  $d = 0.18$ ).

Project ABC has also been evaluated as part of a mixed-methods feasibility study with a sample of UK adolescents (n = 799) (Munir). Quantitative participant feedback, assessed using the Programme Feedback Scale, indicated that most participants found the intervention helpful and enjoyable. At post-test, improvements were reported in hope and self-agency (d=-0.41), hopelessness (d=0.52), and perceived control (d=0.45). The findings suggest Project ABC has promise as a means of providing brief, scalable self-help for depression. However, it is yet to be evaluated with young adults in the UK to establish its feasibility, acceptability and effectiveness.

### **Cost effectiveness**

It is important to measure the cost-effectiveness of SSIs, as scalability and accessibility are only meaningful if interventions are also an efficient use of economic resources. Establishing cost-effectiveness helps inform policy decisions and largescale implementation within health services such as the NHS. Undertaking cost-effectiveness analyses can help determine whether SSIs provide a viable alternative or addition to traditional multisession therapies, particularly in the context of young adult mental health, where service demand exceeds capacity. Despite growing evidence that digital SSIs can alleviate mental health difficulties in young adults, existing studies have not evaluated their economic impact. This represents a significant gap in the literature, as health economic evaluation is essential for establishing the real-world scalability and sustainability of digital SSIs.

## **Objectives**

### **Primary objective**

To determine whether the ABC-UK SSI, in addition to enhanced usual care, results in a reduction in depression symptoms 1-month post-intervention in young adults in the UK compared to enhanced usual care alone (effectiveness RCT). The hypothesis is that the ABC-UK SSI added to enhanced usual care will be superior to enhanced usual care alone.

### **Secondary objectives**

1. Determine whether the ABC-UK SSI, in addition to enhanced usual care, reduces depression symptom severity at 6 months post-intervention, and whether it reduces anxiety symptom

severity, b) improves functioning and c) increases mental well-being at 1month and 6 months.

2. Undertake a health economic evaluation to determine the cost-effectiveness of the ABC-UK SSI.
3. Complete a process evaluation to establish where young adults are recruited from, and interest, uptake, engagement, completion and experience of the intervention and trial.
4. To determine whether any adverse events and/or harms are reported among participants who complete ABC-UK.

### **Study population**

#### **Inclusion criteria**

Participants will be young adults aged 19-25 who live in the UK, are fluent in English, and report elevated depressive symptoms. Participants will be required to have internet access. Eligibility will be determined via completion of a brief (approximately 1-minute) online self-report screener and completion of informed consent procedures. A score of  $\geq 2$  on the Patient Health Questionnaire -2 item version (PHQ-2) will be used to indicate elevated depression symptoms,(Richardson et al., 2010) and will be required in order to be eligible to participate.

#### **Exclusion criteria**

Participants will be excluded if they do not meet the inclusion criteria or if they fail to meet predefined data quality criteria, designed to identify random responding and non-human (e.g. bot) or fraudulent responses. A standard operating procedure (SOP) has been developed for the identification and management of bot and fraudulent responders. Pre-randomisation safeguards will include the use of reCAPTCHA, IP geolocation checks, honeypot items, and attention-check questions. Participants who do not meet these criteria will not be permitted to progress to randomisation. Criteria for identifying suspicious or low-quality responses post-randomisation will be pre-specified in the Statistical Analysis Plan (SAP) and applied during data cleaning. Any exclusions at this stage will be documented and reported. Participants who report active suicidal intent will be excluded. This will be assessed using an item from the Ask Suicide-Screening Questions (ASQ) tool, a brief, validated screening tool for adolescents and adults, developed by the National Institute of Mental Health (NIMH). We will use the question 'Are you having thoughts of killing yourself right now?', with response options 'Yes' and 'No'. If a potential participant selects 'Yes', then they will be ineligible and we will immediately signpost them accessible sources of support, including emergency services.

## Study design

The study will employ a two-arm parallel-group, hybrid Type 1 effectiveness-implementation randomised controlled trial design. Randomisation will be a 1:1 ratio. The trial will be informed by the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation, and Maintenance) (Harden et al., 2024). This framework allows for both evaluation of the effectiveness of the intervention in reducing depressive symptoms, and key implementation outcomes such as feasibility, acceptability and adherence.

## Assessments

The schedule of assessments, and total item count, is presented in Table 1.

### Baseline measures

Demographic variables collected at baseline will be age, biological sex, gender identity, sexual orientation, race/ethnicity and socioeconomic status. We will also ask if the participant lives in Bath/North East Somerset/Swindon/Wiltshire. Additionally, at baseline we will screen for neurodivergence; this will allow for exploratory subgroup analyses of differential intervention effects across participant characteristics.

For neurodivergence, we will use a single-item measure to screen for self-reported neurodivergence. Participants will be asked: *"Do you identify as neurodivergent?"* with response options allowing for multiple forms of identification: *Yes, I identify as autistic (with or without other neurodivergence); Yes, I identify as having ADHD (with or without other neurodivergence); Yes, I identify as neurodivergent but not autistic or as having ADHD; No; and Prefer not to say.* The item is inclusive of both formal diagnoses and self-identification, reflecting a social model of neurodiversity.

A four-item pre-intervention measure of treatment expectancy, developed by the Harvard Lab for Youth Mental Health (Steinberg et al., 2024), will be used to assess participants' expectations of the SSI. Items include statements such as, *"How much do you think you will like doing the online wellness activity?"*, with responses rated on a 10-point scale with 0 being *'not at all'* to and 10 being *'a lot'*. To maintain consistency with the terminology used across our study materials, the phrase *"online wellness activity"* will be changed to *"intervention"*, with the permission of the developer.

### Outcome measures

Outcome measures will be completed at baseline, 1-month post-randomisation and 6-months post-randomisation. 1-month post-randomisation will be the primary endpoint.

Effectiveness outcomes:

The primary outcome will be depressive symptoms at 1-month follow-up.

- Depressive symptoms will be assessed using the Patient Health Questionnaire-9 (PHQ-9) (Kroenke, Spitzer & Williams., 2001), a validated measure for screening and measuring the

degree of depressive symptoms over the past two weeks. The PHQ-9 comprises nine items, rated on a four-point Likert scale, with total scores ranging from 0 to 27. Higher scores reflect greater depressive symptom severity. It has demonstrated strong internal consistency, test-retest reliability, and construct validity (Kroenke, Spitzer & Williams., 2001; Löwe et al., 2004).

The secondary outcomes will be:

- Anxiety symptoms will be assessed using the Generalized Anxiety Disorder-7 Scale (GAD-7) (Spitzer et al., 2006). The GAD-7 measures symptoms of generalised anxiety over the previous two weeks. The scale includes seven items, each rated on a four-point Likert scale from 0 ("not at all") to 3 ("nearly every day"), with total scores ranging from 0 to 21. Higher scores indicate greater anxiety severity. The GAD-7 has strong psychometric properties, including good reliability and validity (Rutter and Brown, 2017).
- Mental wellbeing will be assessed using the Short Warwick–Edinburgh Mental Wellbeing Scale (SWEMWBS; Stewart-Brown et al., 2009). This 7-item scale captures positive aspects of mental health, including emotional wellbeing and psychological functioning, and is derived from the longer 14-item WEMWBS. Items are positively framed and rated on a five-point response scale from "none of the time" to "all of the time," with higher scores reflecting better wellbeing. The SWEMWBS has established internal consistency, test–retest reliability, and construct validity (Ng Fat et al., 2017).
- Functioning will be evaluated using the Outcome Rating Scale (ORS; Prescott et al., 2017), a brief four-item instrument designed to capture key domains of functioning following intervention. These include personal wellbeing, interpersonal relationships, social role functioning (e.g., work or study), and overall functioning. Each domain is rated on a four-point scale, with higher scores indicating better functioning. The ORS has shown strong internal reliability and good concurrent validity with more comprehensive measures (Bringhurst et al., 2006).

#### **Health Economics Outcomes:**

- Resource use will be assessed using a version of the Client Service Receipt Inventory (CSRI; Beecham & Knapp, 2001), which captures participants' use of health and mental health services over the previous six months (e.g., GP visits and support for psychological difficulties). The CSRI has demonstrated good validity, including agreement with administrative records (Mirandola et al., 1999). This measure will be administered at the 6-month follow-up.
- Health-related quality of life will be measured using the EuroQol 5-Dimension 5-Level questionnaire (EQ-5D-5L; Kreimeier et al., 2019). This instrument assesses five domains (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression), each rated across five levels of severity. It also includes a visual analogue scale for overall health. The EQ-5D-5L has demonstrated good reliability and construct validity across a range of populations (Feng et al., 2020).

#### **Implementation Outcomes (intervention arm only)**

- Acceptability and feasibility of the intervention will be assessed using the Programme Feedback Scale (PFS), developed by the Lab for Scalable Mental Health. This 7-item measure uses a five-point Likert scale (1 = strongly disagree to 5 = strongly agree) and includes additional open-ended questions to capture qualitative feedback. Minor wording adaptations have been made (e.g., replacing “kids” with “people”) to ensure appropriateness for a young adult population. Mean item scores above 3 indicate acceptable levels, while scores above 3.5 suggest favourable perceptions (Schleider, Abel & Weisz, 2019; Schleider et al., 2021).
- Participants allocated to the intervention arm will be invited to indicate willingness to take part in follow-up qualitative interviews as part of the process evaluation. A purposive subsample will subsequently be invited to participate.
- Engagement with the intervention will also be assessed by asking participants how often they revisit the intervention materials at both 1-month and 6-month follow-up.
- To better understand barriers to engagement, participants who do not complete the intervention will be contacted via email and invited to complete a brief, anonymous online questionnaire about their experience.

### **Enhanced Usual care**

To monitor enhanced usual care, we will ask participants in both arms if they are currently receiving mental health support, and if they are currently taking medication for mood or anxiety, at baseline and 1-month and 6-month follow-up.

To assess possible contamination, we will ask all participants in the usual care arm at 1-month and 6-months follow-up if they have accessed Project ABC at any point after completing the baseline questionnaire.

### **Adverse effects and harms**

Selected items from two scales for the assessment of adverse effects and harms in psychological therapy will be used – the Negative Effects Questionnaire (NEQ) (Rozenal, 2019) and the Positive and Negative Effects of Psychotherapy Scale for Internet-based Interventions (PANEPS-I) (Baumeister & Moritz, 2022). We have adapted item wording to make them more suitable to the context of single-session self-help interventions. Four items will be used from the NEQ, and 3 items will be used

from the PANEPS-I. Qualitative data provided in free-text boxes for the Programme Feedback Scale will also be used for the assessment of adverse effects and harms.

### Feasibility data

- The CONSORT guidelines (Grant et al., 2018) will be used to report key feasibility data: intervention engagement (initiation of SSI, completion of SSI, time spent on SSI). Feasibility outcomes will also be reported by demographic factors, specifically age, gender identity, ethnic minority status, and socioeconomic status.

**Table 1. Schedule of Study Assessments and item count**

Study assessments	Baseline	Post-Intervention	1 month follow up	6 month follow up	Number of Items
PHQ-2 (initial screen)	X		X	X	2
Demographics + neurodevelopmental disorder screen	X				8
PHQ-9 (remaining 7 items)	X		X	X	7
GAD-7	X		X	X	7
ORS-4	X		X	X	4
SWEMWBS	X		X	X	7
CSRI				X	16
EQ-5D-5L	X		X	X	5
Acceptability of Interventions: PFS (intervention arm only)		X			7
NEQ (intervention arm only)		X			4
PANEPS-I (intervention arm only)		X			3
Treatment Expectancy Measure	X				4
<b>Total number of items</b>	<b>51</b>	<b>19</b>	<b>37</b>	<b>53</b>	

### Participant Pathway

Potential participants will see the study advert via national (e.g. Kooth, Shout) and local organisations or via mail outs and mass media. Those who are interested will click a link or use a QR code on the advert which will direct them to our website which we have codesigned with young adults in the UK,

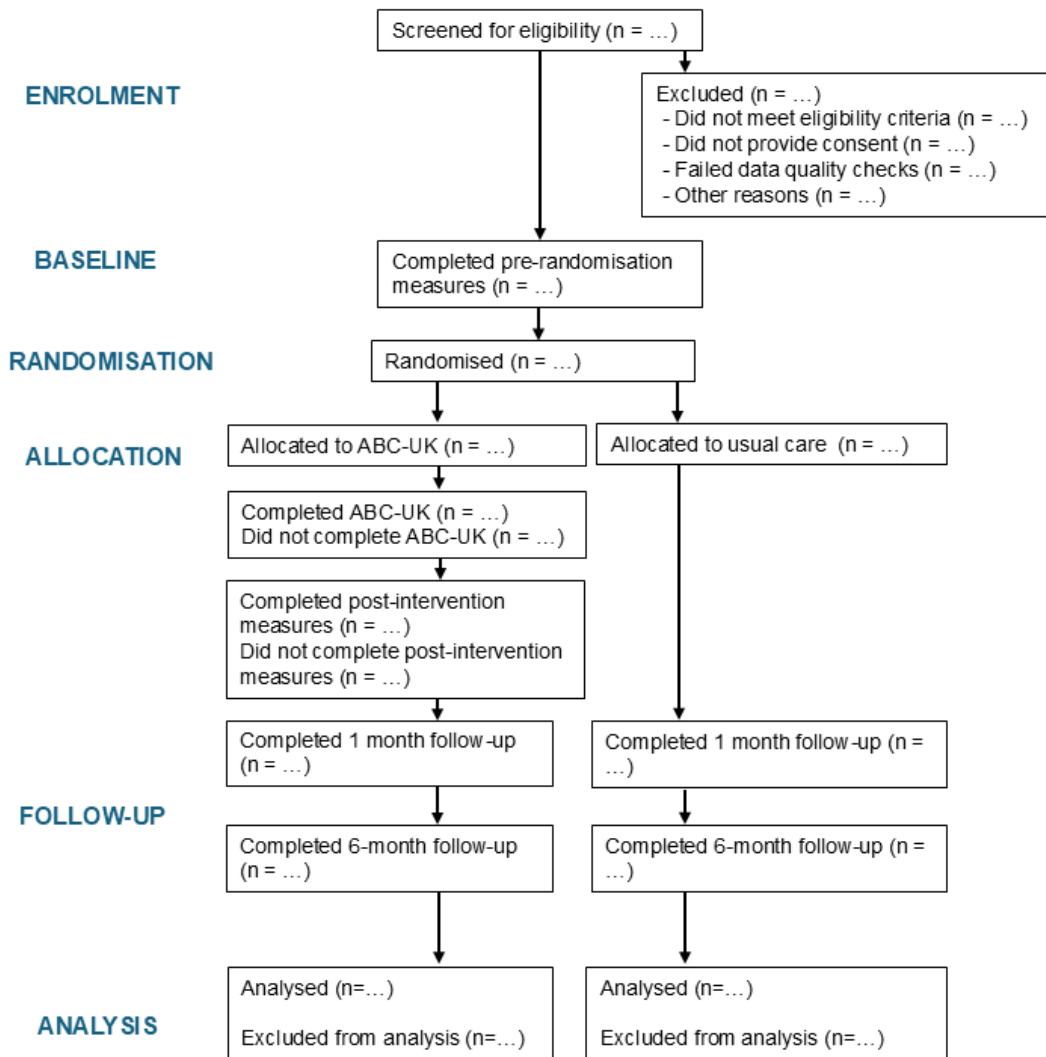
'Unlock Wellbeing' (<https://unlockwellbeing.org.uk/>). From this, interested individuals will click to access more information about the trial, which will direct them to the Qualtrics platform, where they will complete a reCAPTCHA verification step to confirm that responses are provided by a human user and to minimise automated or fraudulent entries. After this they will be directed to the REDCap platform, where they will be presented with the eligibility screening questions. Those who are ineligible will be signposted to sources of support they can access. Those who are eligible will be presented with the participant information sheet (PIS) and consent process. Individuals who consent will be directed to complete baseline measures. Following completion of baseline measures, allocation will be communicated immediately within REDCap via a standardised on-screen message. Participants allocated to the intervention arm will be informed that they have been selected to receive access to the ABC-UK SSI, whilst participants allocated to the enhanced usual care arm will be informed that they will not be completing a self-help activity and will be directed to a mental health resource list.

Post-randomisation, participants allocated to the intervention arm will be presented with a link to click to immediately complete the intervention, which will be hosted on the Qualtrics survey platform. At the end of the intervention, they will be provided with a separate survey link enabling them to re-access the SSI, if they wish to, with the option to have this link emailed to them. Participants will also be provided with the option to download a PDF of their completed activity plan. They will then be asked to complete post-intervention measures on Qualtrics.

All participants who complete the survey will be provided with a debrief sheet within REDCap (or Qualtrics for intervention arm participants at post intervention), immediately after completing the baseline survey and after both follow-ups – this will include a summary of the study aims, reassurance about the voluntary nature of participation, and signposting to mental health support services.

The flow of participants through the trial is presented in Figure 1.

Figure 1. CONSORT Flow Diagram



Follow Up Surveys

All randomised participants will be invited to complete follow-up surveys in REDCap at 1- and 6-months post-randomisation. At baseline, participants will be informed of these timepoints, and approximate survey dates will be provided in advance to encourage planning and improve retention.

For each follow-up survey, an initial email invitation will be sent. Participants who do not complete the survey following this initial invitation will receive two reminder emails: the first 5 working days after the initial invitation, and the second 10 working days after the initial invitation. Reminder emails will be scheduled to be delivered at lunchtime, in line with advice from the YAC that this may facilitate higher completion rates.

Participants may optionally provide their mobile telephone number to enable SMS contact. Those who provide a number will receive (i) up to 3 text message reminders to complete follow-up surveys, and (ii) a brief message at 3 months post-intervention, reminding them of the final follow-up time point at 6 months.

Participants who do not complete the 1-month follow-up will remain eligible to complete the 6-month follow-ups. Additional reminders (beyond the two standard reminder emails) may be issued, should the participants request this at baseline.

### **End of trial**

Participants end their involvement with the trial when their last planned interaction with the study is complete (or efforts to complete this have been unsuccessful), or they have discontinued their participation in the study.

The end of the trial will be defined as the date on which the final study participant completes their last planned study interaction.

## **Table 2. Schedule of Enrolment, Interventions and Assessments**

Time point	Enrolment and Baseline (-t <sub>1</sub> )	Allocation (t <sub>0</sub> )	Intervention (t <sub>1</sub> )	Post-Intervention (t <sub>2</sub> )	1 month follow up (t <sub>3</sub> )	6 month follow up (t <sub>4</sub> )
<b>Enrolment</b>						
Eligibility Screen	X					
Informed Consent	X					
Randomisation		X				
<b>Intervention</b>						
Intervention (ABC-UK SSI)			X			
Usual Care						
<b>Assessments</b>						
Assessments	X			X	X	X

### Recruitment Strategies

Our recruitment strategy is informed by our prior formative SSI work in the UK with young people and young adults (Loades et al., 2024; Jenkins et al., submitted) and by input from our Young Adult Consultants (YAC). We will adopt a multi-faceted approach to recruitment by advertising the study with platforms and organisations where young adults aged 19-25 are known to seek mental health support:

1. Anonymous mental health and well-being platforms: We will advertise on platforms accessed by young adults aged 19-25: Kooth, Shout and Tellmi.
2. University-based support: for example, Student Support services at the University of Bath, University mailing lists
3. Community organisations in Bath and North East Somerset: We will collaborate with local organisations in the region providing mental health and well-being services for individuals aged 19-25 (e.g., Bath Mind, Off the Record Bath, Off the Record Bristol)
4. Mass media: identify and utilise opportunities to discuss the trial in local and national media (TV, radio, print)
5. NIHR Be Part of Research – a free service which allow people to take part in health and care research across the UK

During the initial recruitment phase, we will not utilise social media directly, to help minimise the number of bot responses. We will reconsider this approach if it is necessitated by low recruitment numbers. We also anticipate that community organisations may share some information about the

study on social media, and where they do, we will ask them not to mention the financial incentives for participation to minimise bot driven activity.

### **Incentives**

Participants who complete outcome measures at the primary follow-up time point (1 month follow-up) will receive a £10 shopping voucher. If they complete the second follow-up (6-month follow-up), they will receive an additional £10 shopping voucher.

### **Randomisation**

Randomisation will be implemented using the REDCap survey platform. An independent statistician from the Bristol Trials Centre will generate an allocation list, which will be uploaded to the REDCap randomisation module. Participants will be allocated to one of two intervention conditions, the ABC-UK SSI in addition to enhanced usual care, or enhanced usual care only, on a 1:1 ratio. No member of the research team will have access to the underlying allocation sequence or any function that would allow the prediction of future assignments. No stratification or minimisation procedures will be applied. Within the REDCap survey editor, two blocks corresponding to the two conditions will be created. Randomisation will occur immediately after completion of baseline measures, ensuring allocation is concealed until the participant's allocation is assigned.

### **Blinding**

Participants will be aware of their allocation as those in the control arm will complete no intervention activities, whereas those in the intervention arm will engage with the SSI content. Therefore, blinding of participants will not be possible. No members of the research team will deliver, prompt, or supervise the intervention or control activities. All contact will be automated. The trial manager will have access to allocation for operational purposes but will not be involved in outcome assessment or statistical analysis. A small subset of participants will be purposively sampled for the process evaluation. For these participants, allocation will be known to the researchers involved in interview data collection and analysis.

Data will be exported for analysis with group allocation masked (e.g. coded as Group A and Group B), and primary analyses will be conducted without knowledge of allocation. Participant queries will be managed through a generic study email address. Responses will be limited to procedural or technical support and will not include information about allocation or intervention content. Queries will be handled by a member of the research team.

### **Intervention: Behavioural Activation SSI (BA-SSI)**

The Behavioural Activation SSI, also known as Project Action Brings Change (ABC), is a web-based, self-guided programme that takes approximately 15 to 20 minutes to complete. It is embedded within the Qualtrics online platform and incorporates psychoeducational materials in written and visual formats, brief videos, vignettes, and self-reflective exercises. Personalisation is achieved using branching logic, tailoring some elements to participants' responses.

Participants randomised to the intervention arm will receive access to the BA-SSI in addition to enhanced care as usual (i.e. usual care and a mental health resource list provided to all participants).

The content of SSIs for adolescent and young adult mental health are structured around four key components (Schleider et al., 2020)

- B: Brain science – providing credibility for concepts presented in the programme.
- E: Empowerment - positioning SSI completers in a helper/expert role.
- S: Saying-is-believing exercises - consolidating learning through active engagement.
- T: Testimonials - providing evidence and perspectives from valued others.

The ABC-UK SSI uses the principles of behavioural activation to encourage individuals to engage in value-driven activities in order to improve positive mood. The intervention comprises five core elements:

1. Rationale: introduces the idea that participating in meaningful activities, aligned with your individual values can reduce low mood and low self-esteem.
2. Psychoeducation: Information about the interconnection between behaviour, feelings, and thoughts
3. Values assessment: Asking individuals to identify meaningful areas of life (e.g., family, friendships, academics, hobbies) that currently or previously brought enjoyment and purpose.
4. Activity hierarchy: Guiding individuals to select and personalise three value-based activities for change from pre-generated lists.
5. Benefit–Obstacle–Strategy Exercise: Encouraging individuals to identify potential benefits of engaging in each activity, anticipate obstacles, and develop strategies to overcome them.

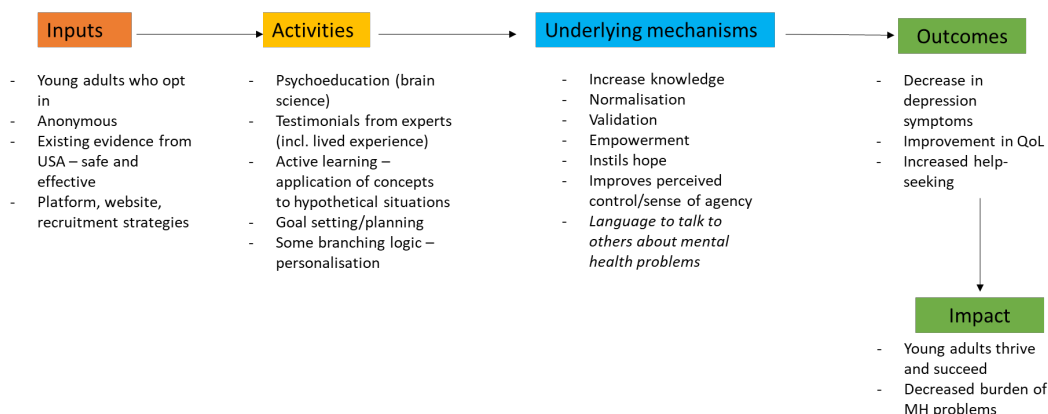
Participants will be able to access the ABC-UK SSI immediately following randomisation. Following initial completion, participants will be able to re-access the intervention materials via a persistent link provided at the end of the SSI and in follow-up communications (e.g., email reminders), enabling them to revisit and reinforce key concepts and planned activities over time.

The materials for the US version of this intervention can be found here: <https://osf.io/ch2tg/>.

The intervention is informed by a logic model outlining hypothesised mechanisms linking intervention components to outcomes (Figure 2).

**Figure 2. Logic model of the intervention**

## Logic Model of the Intervention



Participants in the intervention arm will also continue to be able to access usual care, enhanced by the provision of a mental health resource list post-intervention and at both follow-up points.

### Intervention adaptation

We adapted Project ABC to ensure it is relevant and appropriate for young adults in the UK, and the UK version for young adults is referred to herein as the ABC-UK SSI. The intervention adaptation process was informed by the Person-Based Approach (PBA), a method for developing and adapting behaviour change interventions which centres the experiences and perspectives of individuals who will use them (Yardley et al., 2015). Feedback was collected from young adults in two ways:

- 1) Semi-structured interviews: Conducted via Microsoft Teams with 22 young adults to explore their views of Project ABC (Jenkins et al., submitted). Participants were presented with the SSI and were asked to ‘think aloud’ and share the perceptions of the intervention (likes, dislikes, general reflections), and the relevance of the content to them as young adults.
- 2) Co-adaptation workshop: Held with the YAC, where a member of the research team presented Project ABC and asked the group to reflect on what they would change to make the SSI more suitable for young adults in the UK, and how these changes might be implemented.

The PBA ‘Table of Changes’ tool was used to bring together and categorise feedback and suggested changes. Resulting adaptations to Project ABC included:

- Making examples more relevant to young adults (e.g., referring to university/work and not school)
- Replacing terms with more age-appropriate phrasing (e.g., ‘young adults’ rather than ‘young people’)
- Changing terminology from US to UK terms
- Re-recording voiceovers using British English speaking young adults

- Improvements to the visual design (e.g., standardising fonts and formatting, replacing cartoons with real-life images)
- Substituting video content with material that will resonate with young adults
- The adapted intervention has been named 'ABC-UK'.

## **Comparator**

The comparator condition will be 'enhanced usual care'. This refers to any mental health support, services or resources that a participant would typically access in addition to a standardised mental health resource list provided to all participants at the end of the baseline survey as well as at the end of both follow up surveys as part of the trial. It is not possible to define enhanced usual care precisely as there is considerable potential for variability between what care participants will access, as there is no singular pathway of care for young adult mental health. Additionally, some participants may not engage with any mental health care across the duration of the trial, whilst other participants may engage with a range of supports and services. As part of enhanced care as usual, all participants (in both trial arms) will receive a curated list of mental health resources, including national and local services, which they can access at any time during the study. The support, services and resources that participants may engage with as part of enhanced usual care include, but are not limited to:

- NHS mental health services (e.g., Talking Therapies, Improving Access to Psychological Therapies (IAPT)).
- Primary care support (e.g., GP appointments, prescription medication for psychiatric symptoms)
- Third-sector/voluntary sector support (e.g., Mind, Shout, Samaritans, Kooth)
- Educational or workplace support, such as staff/student well-being services
- Informal support from peers, family and local community groups
- Accessing self-help resources

Participants randomised to the intervention arm will receive access to the ABC-UK single-session intervention (SSI) in addition to enhanced care as usual.

Following completion of the 6-month follow-up assessment, participants allocated to the comparison arm will be offered access to ABC-UK.

The ABC SSI is openly accessible through the Lab for Scalable Mental Health website in the USA. Therefore, it is possible that participants allocated to enhanced usual care may seek this out themselves. To assess possible contamination, we will ask all participants in the enhanced usual care arm at 1-month and 6-months follow-up if they have accessed the ABC SSI at any point after completing the baseline questionnaire.

### **Process evaluation**

A mixed-methods process evaluation will be conducted to examine intervention implementation and mechanisms of action, following the MRC process evaluation guidance (Skivington et al., 2021)

### **Recruitment and reach**

1. Through which recruitment channels are participants reached, and which were most effective?
2. What are the retention rates of participants? What are the reasons for attrition?
3. To what extent are young adults from underrepresented groups recruited to the trial?

### **Intervention fidelity, adherence and dosage**

4. To what extent is the ABC-UK SSI completed as intended?
5. How acceptable do participants find the the ABC-UK SSI and RCT?
6. What are the barriers and facilitators for completion of the ABC-UK SSI and RCT?

### **Intervention mechanisms**

7. How does the ABC-UK SSI differ from enhanced usual care?
8. What are young adults' experiences of the ABC-UK SSI, and perceptions of its impact?
9. Are there any unintended outcomes of completing the ABC-UK SSI?

### **Context**

10. What contextual factors influence participants engagement with the SSI?

### **Qualitative interviews**

After completing the SSI, participants in the intervention arm will be asked in Qualtrics if they are willing to be contacted to participate in qualitative interviews. Selected participants who indicate they are willing to be contacted will be invited via email to participate in qualitative interviews within a month after the completion of the SSI, and provided with a participant information leaflet specific to the interviews. We will aim to interview 20- 30 participants. We will purposively sample young adults to ensure variation across 19-25 age range, with particular efforts to sample participants from underrepresented populations (i.e., young adults from stigmatised and minoritised backgrounds), to ensure a diverse range of perspectives are reflected within the process evaluation.

The interviews will explore experiences and perceived impact of the SSI, using key indicators from the logic model. Interviews will also examine the acceptability of the trial procedures, including recruitment, randomisation, data collection, and barriers and mechanisms to participation in the trial.

The interviews take up to one hour, and will be conducted online on Microsoft Teams by a member of the research team with expertise in undertaking qualitative interviews. Consent will be obtained verbally, at the start of the interview. Interviewed participants will receive a £10 voucher post-interview.

### **Quantitative data**

The following quantitative data will be collected to answer key process evaluation questions:

- Demographics (i.e., participant characteristics data at baseline)
- No. of participants recruited through each avenue (e.g., mental health and well-being platforms, local organisations)
- Dosage data from Qualtrics (e.g. time spent completing the intervention)
- If/how many times was the SSI re-accessed by participants in the intervention arm
- Programme Feedback Scale data (acceptability and feasibility of the SSI)

### **Analysis**

Framework thematic analysis will be used to analyse the qualitative interview data (Gale et al., 2013). Quantitative data will be summarised descriptively. Findings from the qualitative and quantitative data will be triangulated to provide a comprehensive understanding of intervention implementation, mechanisms of action, and acceptability and feasibility of the SSI.

### **Health Economic evaluation**

#### **Objective**

We aim to evaluate the costs and consequences associated with the delivery of ABC-UK SSI + usual care compared to usual care alone after 6 months of follow-up.

#### **Perspective**

We will estimate costs associated with the intervention in Great British Pounds (£) from the healthcare payer perspective (primary) and a broader societal perspective (secondary).

#### **Time Horizon**

The consequences will be assessed at baseline, 1m and 6m post-intervention, and the costs will be assessed at 6 m (i.e. short to medium term).

#### **Outcomes measured**

- Health-related quality of Life measured using the EQ-5D-5L.

See measures section above for further details of outcome measures.

#### **Cost Identification and Measurement**

Cost data will include:

- Intervention costs (e.g., Qualtrics licence, maintenance of SSIs)
- Service use from the perspective of the NHS: Self-reported resource use (CSRI) focusing on GP, A&E visits for mental health emergency care, NHS mental health services
- Productivity loss: Absenteeism/presenteeism in education and the workplace (societal perspective).

### **Data analysis**

We will provide a descriptive summary of costs and outcomes by group, charting incremental cost and outcome differences. We will not aggregate costs and outcomes into a single metric. To account for uncertainty (e.g. alternative unit costs, missing data assumptions), we will run sensitivity analyses with different cost assumptions and definitions of effectiveness.

### **Implementation: Cost effectiveness of different recruitment strategies**

We will also explore the cost effectiveness of different recruitment strategies. Our research question is:

What is the cost effectiveness of promotion via mass media (TV, radio) versus promotion via community organisations (Bath Mind, Off the Record Bath) versus promotion via national UK organisations that provide early help (Kooth, Shout)?

To allow readers to compare the costs and outcomes of different recruitment strategies, we will tabulate total costs of each recruitment strategy and will report the number of target population recruited via this strategy as the desired outcome of the implementation strategies. We will report the participant characteristics of those recruited, focusing on under-served populations (e.g. numbers of ethnic minorities, LGBTQIA+) recruited via each implementation strategy. This analysis will assume that number recruited equates to number who benefitted, irrespective of whether they fully completed the single session intervention (i.e. Intention to Treat). We will conduct a sensitivity analysis to look instead at numbers who completed the intervention (i.e. Completers).

### **Data Management**

We will follow the University of Bath guidance for data management (<https://www.bath.ac.uk/guides/research-data-policy-guidance/>). As Chief Investigator, Dr Jeffrey Lambert will act as the data steward.

All questionnaire data capture will take place electronically on the REDCap and Qualtrics survey platforms, with no paper data collection. Data downloaded from REDCap and Qualtrics will be stored securely on the University of Bath server, within a trial specific folder. Access to this folder will be managed by the Chief Investigator.

For individuals who opt to participate in the process evaluation interviews, Microsoft Teams will be used to conduct and record the interviews, with the automatic transcription function enabled. The research team will review and edit the transcripts for accuracy against the original recordings before the recordings are permanently deleted. Finalised interview transcripts will be securely stored on the University of Bath server within a trial specific folder. Access to this folder will be managed by the Chief Investigator.

### **Source Data**

All source data will be generated directly by the study. These data will be self-report questionnaire data in REDCap and Qualtrics, Qualtrics usage metrics (e.g., time spent completing the SSI), and transcripts from qualitative process evaluation interviews.

### **Confidentiality**

#### **Trial participants**

Participants in the trial will have pseudo-anonymity. We will ask participants to provide their email address to facilitate contact for completion of follow-up measures, and to link data between REDCap and Qualtrics (for the intervention arm only) Participants can also optionally provide their mobile phone number to receive reminders to complete follow-up measures. No other personal data will be collected.

Participants may choose to share personally identifiable information as part of the free text responses – should this occur, the information will be anonymised during the data cleaning process.

Process evaluation participants: Participants partaking in qualitative interviews will be asked to share their first name, to facilitate a good rapport. Their name will be recorded in the REDCap consent forms, and the interview transcripts, which will be anonymised during the data cleaning process. No other personal data will be collected.

### **Record retention and archiving**

In accordance with University of Bath policy, data will be retained for a period of 10 years from the publication date of any research findings based on the project, or 10 years from the end of the project, whichever is later.

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

The risk assessment process is a careful examination of what could cause harm, who/what could be harmed and how, and risks to the study integrity. Reasonably foreseeable risks associated with a research study, and actions to control the risks so far as is reasonably practicable, will be identified and documented as soon as possible in a study specific risk assessment.

The risk assessment documentation and any subsequent revisions will be kept in the TMF. The risk assessment will be an ongoing process. Each time there are changes to the perceived risks and mitigating circumstances these will be agreed by the TMG and CI and documented.

As participants will be pseudo-anonymous, and given the large sample size and the self-help nature of the intervention, it will not be possible to provide individual risk assessments or conduct direct follow-up with participants.

At baseline and follow-up assessments, suicidal ideation will be explicitly screened using item 9 of the PHQ-9, which asks: *“Thoughts that you would be better off dead, or of hurting yourself in some way?”*

If participants select a response of ‘2’ (more than half the days) or ‘3’ (nearly every day) on this item, additional signposting to immediately available sources of support will be automatically triggered within the REDCap platform to provide timely help.

## **Monitoring**

Monitoring is defined as the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirements.

The purpose of monitoring is to verify that:

- The rights and well-being of the participants are protected;
- The reported study data are accurate, complete and verifiable from source documents;
- The conduct of the study complies with the currently approved protocol, GCP and the applicable regulatory requirements.

Study monitoring activities should be identified based on the study specific risk assessment and will be documented in a Monitoring Plan/Quality management plan. This will be developed by the trial team based on the trial risk assessment.

### **Monitoring of study by Sponsor**

The trial will be monitored and audited in accordance with the Sponsor’s policy, which is consistent with the UK Policy Framework for Health and Social Care Research. All trial related documents will be made available on request for monitoring and audit by the Sponsor and the relevant REC.

### **Monitoring of study by study team**

The Sponsor usually delegates some monitoring activities to the central trial team. Checks of the following would be typical:

- Informed Consent process and documentation
- Inclusion and Exclusion criteria verification
- Completed source documents and data completeness and other types of data queries
- Study procedures and / or intervention compliance
- Safety documentation and adverse event reporting
- Protocol deviations

The trial database will have in-built validation and the TMG will review the completeness of the data throughout the trial. The quality of the study data may be monitored through centralised database monitoring. Validation checks are documented in the database specification document. Data completeness and accuracy checks may be run through the study databases. Data queries are usually reported via the study database and may be supplemented by additional independent data checks carried out by the study statistical team.

### **Protocol compliance**

Prospective, planned deviations or waivers to the protocol are not allowed. Accidental protocol deviations will be documented and reported to the CI and Sponsor in line with the Sponsor's reporting requirements. They will also be reported to the DMSC. In the event of systematic protocol deviations, investigation and remedial action will be taken in liaison with the CI, TSC and the TMG.

Sponsor specific procedures will be followed for the reporting of any breaches.

Sponsor will determine whether it constitutes a serious breach, requiring onward reporting to the REC.

Serious Breaches to GCP and/or the protocol

A "serious breach" is a breach which is likely to affect to a significant degree:

- a. the safety or physical or mental integrity of the subjects of the trial; or
- b. the scientific value of the trial.

If a breach of GCP or protocol occurs during a trial, this may be identified through routine monitoring, internal audits or during the day to day running of the trial. The CI will make an assessment of the severity of the breach. If the breach is classified by the PI as a 'serious breach' according to the definition above, the PI will complete a 'Notification of Serious Breach of GCP or Trial Protocol Form'. The PI will scan and email the notification form over to the Vice-Chancellor's Office within 24hrs of becoming aware of the breach via [pro-vc-research@bath.ac.uk](mailto:pro-vc-research@bath.ac.uk). It is the responsibility of the Sponsor to assess the impact of the breach on the scientific value of the trial.

## **Safety Recording and Reporting**

### **Definitions**

#### *Adverse Event*

An adverse event (AE) is any untoward or undesirable medical occurrence in a subject receiving treatment according to the protocol. This includes occurrences which are not necessarily caused by or related to administration of the research procedures.

#### *Adverse Reaction*

An adverse reaction (AR) is any undesirable experience that has happened to a subject that is suspected to be caused by the intervention.

#### *Serious Adverse Event*

A serious adverse event (SAE) is any adverse event which:

- results in death,
- is / was life threatening\*,
- requires hospitalisation or prolongs an ongoing hospitalisation\*\*,
- results in persistent or significant disability or incapacity,
- consists of a congenital anomaly or birth defect,

Other important medical events that may jeopardise the subject and may require medical or surgical intervention to prevent one of the outcomes listed above should also be classed as an SAE.

*\*"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.*

*\*\*"Hospitalisation" is defined as an unplanned overnight stay. Note, however, that the patient must be formally admitted – waiting in outpatients or an Emergency Department would not count as hospitalisation (even though this can sometimes be overnight). Planned hospital stays would not be counted as SAEs, nor would time in hospital for "social reasons" (e.g. respite care, the fact that there is no-one at home to care for the patient). Also, if patients had a day-case operation, this would not qualify as hospitalisation. However, if a planned operation was brought forward because of worsening symptoms, this would be considered as an SAE. Hospitalisations for the purpose of the intervention are an exception to SAE reporting unless complications occur.*

#### *Suspected Serious Adverse Reaction*

A suspected serious adverse reaction (SSAR) is any serious adverse event that is suspected to be related to the intervention.

#### *Suspected Unexpected Serious Adverse Reaction*

A suspected unexpected serious adverse reaction (SUSAR) is serious adverse event that is not consistent with the defined anticipated or expected events (below) and is assessed as being possibly, probably or definitely related to the intervention.

#### **Reporting period**

The reporting period for the study will be from the point of consent to the end of the 6-month follow-up window.

#### **Reporting overview**

There are multiple routes through which participants may disclose adverse events (see separate SOPs on monitoring, classification, and reporting for full procedures) and through which potential safety issues may be identified in this study:

1. Qualtrics intervention freetext responses:  
Participants may disclose adverse events via freetext responses within the Qualtrics delivered intervention. These responses will be reviewed on a weekly basis.

## 2. Qualtrics PFS freetext responses:

Participants may also disclose adverse events through freetext responses within the postintervention PFS completed in Qualtrics. They will be monitored weekly.

## 3. Direct contact with the study team:

Participants may contact the study team directly via the study email address. This inbox will be monitored by a member of the study team at least every two working days.

In addition, data relating to harm will be generated monthly based on responses to the post-intervention harm related items (the seven items from the NEQ and PANEPSII). These summaries will be reviewed by the Chief Investigator and presented as a standing item at each monthly TMG meeting and each 6 monthly TSC meeting for the duration of participant recruitment.

Once the first participant reaches their 6-month follow-up assessment, monthly summaries of A&E attendance derived from CSRI data will also be generated and reviewed in the same manner. This process will continue until the final participant has completed their final follow-up.

Adverse event (AE)	Record in source data Record assessment of causality, severity and seriousness, as conducted by the CI
Adverse reaction (AR)	Record in source data Record assessment of causality, severity and seriousness, as conducted by the CI
Serious adverse event (SAE)	Record in source data Record assessment of causality, severity and seriousness, as conducted by the CI Report to trial team within 24h of becoming aware (who will report on to Sponsor/REC within 2 working days)
Suspected serious adverse reaction (SSAR)	Record in source data Record assessment of causality, severity and seriousness, as conducted by the CI Report to trial team within 24h of becoming aware (who will report on to Sponsor/REC within 24h)
Suspected unexpected serious adverse reaction (SUSAR)	Record in source data Record assessment of causality, severity and seriousness, as conducted by the CI

	Report to trial team within 24h of becoming aware (who will report on to Sponsor/REC within 2 working days)
--	---

All safety information, including information relating to safety events that are not subject to expedited reporting but are captured as trial endpoints, will be closely monitored by the TSC throughout the trial. The TSC will be provided with a report at least annually.

### **Adverse Events and Serious Adverse Events**

The trial will be conducted anonymously and online with participants who are reporting symptoms of depression. Possible adverse events (AE) that may be likely in this population are:

- Low risk acts of self-harm (not requiring medical attention) e.g., scratching.
- Suicidal thoughts without specific plans or intent

Possible adverse events (AE) and serious adverse events (SAE) that are less likely but may still occur are:

- High risk acts of self-harm (requiring medical attention, e.g. deep cuts to the body, or medical hospital admission).
- Suicidal behaviour with plans and intent to act
- Significant and sustained deterioration of a pre-existing mental health condition that required immediate intervention
- Voluntary admission to a psychiatric hospital
- Sectioned under the Mental Health Act
- Serious safeguarding issues
- Death by suicide

If a potential AE or SAE is identified, the Chief Investigator will be notified immediately. If unavailable, another senior member of the Bath Mental Health Research Group will be consulted. The CI/senior staff member will assess whether the AE or SAE meets the criteria for reporting under University of Bath adverse event guidelines.

All SAEs will be reported to the Psychology Experimental Officers [psy-experimental-officer@bath.ac.uk](mailto:psy-experimental-officer@bath.ac.uk), in line with the Department of Psychology reporting procedure <https://computingservices.sharepoint.com/sites/PsychologyResearchHub/SitePages/Unexpected-Events-and-Complaints.aspx>. The SAE will also be reported to the University of Bath Research Ethics Committee (REC) by email to [research-ethics@bath.ac.uk](mailto:research-ethics@bath.ac.uk) cc [research-governance@bath.ac.uk](mailto:research-governance@bath.ac.uk),

including the original study approval reference (REC Approval Reference number). All SAEs will be reported within 2 working days of the identification by the team member.

Direct follow-up is not possible, if AEs/SAEs are reported, as we have limited information about participants, and limited capacity as a research team to respond to and manage clinical follow ups in a timely and appropriate manner. To ensure transparency, a disclaimer will be included in the participant information sheet and survey introduction, stating:

“If you are in distress or need support, we encourage you to speak to someone you trust, and/or to contact any of the following sources of support on our mental health resource list. While we do collect your email address in this study, we cannot contact you individually to check in.”

### **Urgent safety measures**

The Sponsor and investigator may take appropriate urgent safety measures (USM) to protect a research participant from an immediate hazard to their health and safety. This USM can be taken before seeking approval from the competent authorities and ethics committee.

The main research ethics committee must be notified by email within three days. Information should include that such measures have been taken and the reasons why. Where the USM requires an amendment to study documentation, this should be submitted as a substantial amendment as soon as possible and marked as being in response to USM. A copy of the USM notification should be submitted with the amendment.

If the Principal Investigator (and not the sponsor) has instigated the USM, the sponsor should be notified immediately so that they can assess and report the USM within the timelines required.

Where applicable, oversight committees (such as the TSC) should review information relating to USM and report any recommendations to all relevant parties. The funder should be updated on all developments and actions as soon as possible.

### **Statistical considerations**

Statistical analyses will be conducted by a statistician at the University of Bath. A full detailed statistical analysis plan (SAP) will be developed by the trial statistician, and agreed by the Trial Steering Committee (TSC) prior to final analysis. Participant baseline characteristics will be reported descriptively using appropriate numerical and categorical summaries.

### **Sample Size**

To detect a clinically meaningful difference of 2 points on the PHQ-9 (Bauer-Staeb et al., 2021), we assume a standard deviation of 5.0 (Keum et al., 2018; Osborn et al., 2019) and a baseline-follow-up correlation of 0.5. With 90% power and a significance level of 5%, the required sample size per group is 99 participants. Anticipating a 25% attrition rate based on previous trials of SSIs (Cohen & Schleider, 2022), we plan to recruit 264 participants in total.

### *Primary analysis*

The primary outcome is depression symptoms measured by PHQ-9 assessed at 1-month post-randomisation. The primary outcome will be compared between the comparator arm and the intervention arm.

The primary analysis model will be a linear mixed-effects model that accounts for the correlation of pre- and post-randomisation outcome measures within patients, using all non-missing data on these outcomes. An interaction effect for randomised group and post-randomisation time point will be included to enable estimation of treatment effects at each time point. Model validity will be checked using standard methods; if a model is a poor fit, alternative models or transformations will be explored.

The primary analysis will include a random effect to allow for clustering within individuals. The following covariates will be adjusted for in the primary outcome analysis model as fixed effects:

- Age in years (continuous)
- Gender (categorical: male, female, other/prefer not to say)
- Baseline depression symptom severity (continuous, measured by PHQ-9)

The primary analysis will take place when follow-up is complete for all recruited patients, i.e., at 7 months post randomisation. No interim analysis of outcomes is planned. Safety data will be reported to the TSC at a frequency agreed by the committee, together with any additional analyses the committee request.

Baseline characteristics will be summarised descriptively by condition to check for chance imbalance. Any imbalance will not alter the primary intention-to-treat analysis but may be explored in prespecified sensitivity analyses.

### *Secondary analyses*

#### *Analysis of secondary outcome measures*

The analysis of secondary clinical outcome measures will be conducted following a treatment policy strategy. As these outcomes are all continuous, the same method used for the primary outcome will be applied.

#### *Sub-group analyses*

Sub-group analyses of outcomes will be conducted. These analyses will be exploratory in nature, and pre-specified in the SAP prior to analysis commencing.

#### *Sensitivity Analyses*

#### *Missing data*

We will analyse all non-missing data for the primary outcome, which is a valid approach providing the outcome data is missing at random. If an appreciable proportion of primary outcome data are

missing, we will do a sensitivity analyses to investigate the sensitivity of our conclusions to deviations from the assumption of missing at random.

#### *Exclusion of process-evaluation participants*

We will repeat the main outcomes analysis, excluding those participants who take part in process evaluation interviews, due to the potential that being involved in the interviews post-intervention may influence outcomes by offering a warm, non-judgemental, listening space.

#### *Software and Reporting*

All statistical analyses will be conducted using R Studio, unless otherwise specified. Results will be reported according to the CONSORT guidelines for reporting psychological interventions (Grant et al., 2018), the CONSORT guidelines for reporting randomised controlled trials (Hopewell et al., 2025), including effect sizes and confidence intervals, and the CHERRIES checklist for the reporting of e-surveys (Eysenbach et al., 2004). Any deviations from this plan will be documented and justified in the full SAP.

## **Ethics**

### **Ethical Approval**

Ethical will be obtained from a University of Bath Research Ethics Committee.

### **Informed Consent Procedures**

After completing eligibility checks in the REDCap database, participants will be presented with an information sheet and consent form. Participants will then be asked to indicate whether they consent to participate. Those who do not provide consent will be ineligible for the study and will instead be signposted to alternative sources of support. No identifiable data will be collected as part of eligibility checks. Any data retained from eligibility screening will be analysed and reported in aggregate form only.

### **Public and patient Involvement**

We have an advisory group of 12 young adults aged 19-25, known as the Young Adult Consultants (YAC) contributing to the development of the study. Young adults were recruited through the University of Bath, local organisations in Bath, and national organisations in the UK. The group is diverse in terms of ethnicity, gender identity and socio-economic status; some group members also have lived experiences of mental health difficulties.

The YAC have guided several key trial decisions around selection of the trial name, outcomes measures, follow-up time points, voucher incentives and strategies for maintaining engagement. We also consulted with the YAC in order to adapt the Project ABC SSI to make it suitable for young adults in the UK (this process is described in the *Intervention* section above).

We will continue to consult with the YAC regarding problem-solving and decision-making throughout the duration of the trial. We will also engage the YAC to support with the dissemination of the findings after the trial is complete. Additionally, a young adult lay representative will sit on the Trial Steering Committee (TSC).

### **Roles and Responsibilities**

The Chief Investigator (CI) will have overall responsibility for the day-to-day conduct and management of the trial. Specific responsibilities include:

- Ensuring the trial is conducted in accordance with the protocol, Good Clinical Practice (GCP), and all applicable regulatory and ethical requirements.
- Ensuring any adverse events (AEs) reported by participants during the trial are identified and reported to the appropriate regulatory bodies and managed in line with the study protocol and relevant guidelines.
- Conducting regular safety assessments and reviewing safety data to identify any emerging patterns or concerns related to adverse events.

### **Trial Committees**

#### *Trial Management Group (TMG)*

The Trial Management Group (TMG) will meet on a monthly basis throughout the duration of the trial. Membership will include all members of the trial team from University of Bath and Bristol Trials Centre. The TMG will oversee all aspects of trial delivery and will:

- Provide specialist advice during trial set-up, including input into trial procedures and documentation (e.g., participant information sheets and consent forms, trial protocol).
- Advise on trial recruitment strategies, and operational challenges.
- Monitor trial progress and address any challenges or risks (e.g., serious adverse events or safety issues) as they occur

#### *Trial Steering Committee (TSC)*

The Trial Steering Committee (TSC) will provide independent oversight of the trial. The TSC will consist of an independent Chair with relevant expertise and three other independent members, including a young adult lay representatives and a statistician. Non-independent members will include the Chief Investigators, Trial Manager and Trial Statistician.

The TSC will meet bi-annually, with additional meetings convened at the discretion of the TSC Chair, if required. The TSC will:

- Provide overall supervision for the trial, offering independent advice through the Chair.
- Review trial conduct, progress, and any emerging issues.
- Make recommendations on the continuation or modification of the trial.

All members will be required to sign the TSC Charter, outlining their remit and responsibilities.

#### *Data Monitoring Committee (DMC)*

The Trial Steering Committee (TSC) will determine whether a separate Data Monitoring Committee (DMC) is required for this trial. If the TSC decides that a DMC is necessary, all DMC members will be required to sign the DMC Charter, which will outline the remit, responsibilities, and conditions of membership.

#### **Finance and Funding**

This work is funded by the NIHR Bath Mental Health Research Group (NIHR207583). The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR, NHS or the UK Department of Health and Social Care.

#### **Indemnity**

The University of Bath has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University.

The University of Bath holds Professional Indemnity insurance to cover the legal liability of the University as Research Sponsor and/or as the employer of staff engaged in the research, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

The University of Bath's Public Liability and Professional Indemnity insurance policies provide an indemnity to our employees for their potential liability for harm to participants during the conduct of the research.

#### **Dissemination Policy**

The main findings will be published in a peer review journal, with authorship determined in advance with the TMG. Findings will also be presented at national and international academic conferences to ensure engagement with researchers, practitioners, and other stakeholders in mental health research and practice.

To maximise reach beyond academic audiences, we will also share the findings on social media channels such as LinkedIn and BlueSky, and in mass media (e.g., a press release from the UoBath media office, and in podcasts/blogs.)

**Revision History**

Document ID - (Document Title) revision X.Y	Description of changes from previous revision	Effective Date
Version 1.0	n/a	February 2026
Version 1.1	Revised GAD-2 to GAD-7	March 2026
Version 1.2	Revised to reflect post-intervention measures moved from REDCap to Qualtrics	April 2026



## References

- American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). <https://doi.org/10.1176/appi.books.9780890425596>
- Beecham, J., and Knapp, M. R. J. (2001) *Costing psychiatric interventions*. In: Thornicroft, Graham, ed. *Measuring Mental Health Needs* (Second Edition). Royal College of Psychiatrists, London, pp. 200-224.
- British Medical Association, 2025 <https://www.bma.org.uk/advice-and-support/nhs-delivery-and-workforce/pressures/mental-health-pressures-data-analysis#:~:text=It%20is%20to%20be%20welcomed,need%20to%20be%20urgently%20addressed>
- Bringhurst, D. L., Watson, C. W., Miller, S. D., & Duncan, B. L. (2006). *The reliability and validity of the Outcome Rating Scale: A replication study of a brief clinical measure*. *Journal of Brief Therapy*, 5(1), 23–30.
- Bruffaerts, R., Mortier, P., Kiekens, G., Auerbach, R. P., Cuijpers, P., Demyttenaere, K., ... & Kessler, R. C. (2018). Mental health problems in college freshmen: Prevalence and academic functioning. *Journal of affective disorders*, 225, 97-103.
- Byrd-Bredbenner, C., Eck, K., & Quick, V. (2021). GAD-7, GAD-2, and GAD-mini: Psychometric properties and norms of university students in the United States. *Gen Hosp Psychiatry*, 69, 61-66.
- Cohen, K. A., & Schleider, J. L. (2022). Adolescent dropout from brief digital mental health interventions within and beyond randomized trials. *Internet interventions*, 27, 100496. <https://doi.org/10.1016/j.invent.2022.100496>
- Colizzi, M., Lasalvia, A. & Ruggeri, M. Prevention and early intervention in youth mental health: is it time for a multidisciplinary and trans-diagnostic model for care?. *Int J Ment Health Syst* 14, 23 (2020). <https://doi.org/10.1186/s13033-020-00356-9>
- Dumontheil I. (2016). Adolescent brain development. *Current Opinion in Behavioral Sciences*, 10, 39–44. <https://doi.org/10.1016/j.cobeha.2016.04.012>
- Eylem, O., de Wit, L., van Straten, A., Steubl, L., Melissourgaki, Z., Danişman, G. T., de Vries, R., Kerkhof, A. J. F. M., Bhui, K., & Cuijpers, P. (2020). Stigma for common mental disorders in racial minorities and majorities a systematic review and meta-analysis. *BMC public health*, 20(1), 879. <https://doi.org/10.1186/s12889-020-08964-3>
- Eysenbach G. (2004). Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). *Journal of medical Internet research*, 6(3), e34. <https://doi.org/10.2196/jmir.6.3.e34>
- Feng, Y. S., Kohlmann, T., Janssen, M. F., & Buchholz, I. (2021). Psychometric properties of the EQ-5D-5L: a systematic review of the literature. *Quality of life research : an international journal of quality of life aspects of treatment, care and rehabilitation*, 30(3), 647–673. <https://doi.org/10.1007/s11136-020-02688-y>

- Fleming, T., Bavin, L., Lucassen, M., Stasiak, K., Hopkins, S., & Merry, S. (2018). Beyond the Trial: Systematic Review of Real-World Uptake and Engagement With Digital Self-Help Interventions for Depression, Low Mood, or Anxiety. *Journal of medical Internet research*, 20(6), e199. <https://doi.org/10.2196/jmir.9275>
- Gale, N. K., Heath, G., Cameron, E., Rashid, S., & Redwood, S. (2013). Using the framework method for the analysis of qualitative data in multi-disciplinary health research. *BMC medical research methodology*, 13(1), 117.
- Gore, F. M., Bloem, P. J., Patton, G. C., Ferguson, J., Joseph, V., Coffey, C., ... & Mathers, C. D. (2011). Global burden of disease in young people aged 10–24 years: a systematic analysis. *The Lancet*, 377(9783), 2093-2102.
- Grant, S., Mayo-Wilson, E., Montgomery, P., Macdonald, G., Michie, S., Hopewell, S., & Moher, D., on behalf of the CONSORT-SPI Group. (2018). Reporting randomized trials of social and psychological interventions: The CONSORT-SPI 2018 extension. *Trials*, 19, Article 407.
- Gulliver, A., Griffiths, K.M. & Christensen, H. Perceived barriers and facilitators to mental health help-seeking in young people: a systematic review. *BMC Psychiatry* 10, 113 (2010). <https://doi.org/10.1186/1471-244X-10-113>
- Hollis, C., Loades, M., & Hall, C. L. (2025). Digital technology: Assessment and treatment. In A. Thapar, D. S. Pine, S. Cortese, C. Creswell, T. J. Ford, & J. F. Leckman (Eds.), *Rutter's child and adolescent psychiatry and psychology* (pp. 633–651). John Wiley & Sons.
- Hopewell S, Chan AW, Collins GS, Hróbjartsson A, Moher D, Schulz KF, et al. CONSORT 2025 Statement: updated guideline for reporting randomised trials. *BMJ*. 2025; 388:e081123. <https://dx.doi.org/10.1136/bmj-2024-081123>
- Jacobson, N. S., Martell, C. R., & Dimidjian, S. (2001). Behavioral activation treatment for depression: Returning to contextual roots. *Clinical Psychology: Science and Practice*, 8(3), 255–270. <https://doi.org/10.1093/clipsy.8.3.255>
- Jia, E., Macon, J., Doering, M., & Abraham, J. (2025). Effectiveness of Digital Behavioral Activation Interventions for Depression and Anxiety: Systematic Review and Meta-Analysis. *Journal of Medical Internet Research*, 27, e68054.
- König, H., König, H.-H., & Konnopka, A. (2020). The excess costs of depression: a systematic review and meta-analysis. *Epidemiology and Psychiatric Sciences*, 29, e30. doi:10.1017/S2045796019000180
- Kreimeier S, Åström M, Burström K, Egmar AC, Gusi N, Herdman M, Kind P, Perez MA, Greiner W. (2019). EQ-5D-Y-5L: developing a revised EQ-5D-Y with increased response categories. *Quality of Life Research*, 28, 1951-1961.
- Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001). The PHQ-9: validity of a brief depression severity measure. *Journal of general internal medicine*, 16(9), 606–613. <https://doi.org/10.1046/j.1525-1497.2001.016009606.x>
- Li, W., Zhao, Z., Chen, D., Peng, Y. and Lu, Z. (2022), Prevalence and associated factors of depression and anxiety symptoms among college students: a systematic review and meta-analysis. *J Child Psychol Psychiatr*, 63: 1222-1230. <https://doi.org/10.1111/jcpp.13606>

- Linardon, J., Torous, J., Firth, J., Cuijpers, P., Messer, M., & Fuller-Tyszkiewicz, M. (2024). Current evidence on the efficacy of mental health smartphone apps for symptoms of depression and anxiety. A meta-analysis of 176 randomized controlled trials. *World psychiatry : official journal of the World Psychiatric Association (WPA)*, 23(1), 139–149. <https://doi.org/10.1002/wps.21183>
- Loades M. E. (2025) Recognizing continued development beyond the adolescent years: Clinical child psychology and psychiatry spans early adulthood. *Clinical Child Psychology and Psychiatry*. 2025;30(3):531-536. doi:[10.1177/13591045251346290](https://doi.org/10.1177/13591045251346290)
- Löwe, B., Kroenke, K., Herzog, W., & Gräfe, K. (2004). Measuring depression outcome with a brief self-report instrument: Sensitivity to change of the Patient Health Questionnaire (PHQ-9). *Journal of Affective Disorders*, 81(1), 61–66. <https://doi.org/10.1016/j.jad.2004.02.006>
- Nakonezny, P. A., Carmody, T. J., Morris, D. W., Kurian, B. T., & Trivedi, M. H. (2010). Psychometric evaluation of the Snaith–Hamilton Pleasure Scale in adult outpatients with major depressive disorder. *International Clinical Psychopharmacology*, 25(6), 328–333. <https://doi.org/10.1097/YIC.0b013e32833eb5ee>
- Ng Fat, L., Scholes, S., Boniface, S., Mindell, J., & Stewart-Brown, S. (2017). *Evaluating and establishing national norms for mental wellbeing using the Short Warwick–Edinburgh Mental Well-being Scale (SWEMWBS): Findings from the Health Survey for England*. *Quality of Life Research*, 26(5), 1129–1144.
- ONS, 2024  
<https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/articles/milestonesjourneyingthroughmodernlife/2024-04-08>
- Prescott, D. S., Maeschalck, C. L., & Miller, S. D. (2017). *Feedback-informed treatment in clinical practice: Reaching for excellence*. Washington, DC: American Psychological Association. <https://doi.org/10.1037/0000024-000>
- Punton, G., Dodd, A. L., & McNeill, A. (2022). 'You're on the waiting list': An interpretive phenomenological analysis of young adults' experiences of waiting lists within mental health services in the UK. *PLoS one*, 17(3), e0265542. <https://doi.org/10.1371/journal.pone.0265542>
- Riddle, D.B., Appenzeller, Z.S., Storch, E.A. (2024). Emerging Adulthood and Depression: An Overview of Chronic Illness and Treatment. In: Kuo, A.A., Pilapil, M., DeLaet, D.E., Peacock, C., Sharma, N. (eds) *Care of Adults with Chronic Childhood Conditions*. Springer, Cham. [https://doi.org/10.1007/978-3-031-54281-7\\_17](https://doi.org/10.1007/978-3-031-54281-7_17)
- Rozental, A., Kottorp, A., Forsström, D., Månsson, K., Boettcher, J., Andersson, G., ... Carlbring, P. (2019). The Negative Effects Questionnaire: psychometric properties of an instrument for assessing negative effects in psychological treatments. *Behavioural and Cognitive Psychotherapy*, 47(5), 559–572. doi:10.1017/S1352465819000018
- Rutter, L.A., Brown, T.A. Psychometric Properties of the Generalized Anxiety Disorder Scale-7 (GAD-7) in Outpatients with Anxiety and Mood Disorders. *J Psychopathol Behav Assess* 39, 140–146 (2017). <https://doi.org/10.1007/s10862-016-9571-9>

- Schleider JL, Dobias M, Sung J, Mumper E, Mullarkey MC. Acceptability and utility of an open-access, online single-session intervention platform for adolescent mental health. *JMIR Ment Health*. 2020 Jun 30;7(6):e20513. doi: 10.2196/20513. <https://mental.jmir.org/2020/6/e20513/>
- Schleider, J. L., Abel, M. R., & Weisz, J. R. (2019). Do Immediate Gains Predict Long-Term Symptom Change? Findings from a Randomized Trial of a Single-Session Intervention for Youth Anxiety and Depression. *Child Psychiatry Hum Dev*, 50(5), 868-881. <https://doi.org/10.1007/s10578-019-00889-2>
- Schleider, J. L., Mullarkey, M. C., Fox, K. R., Dobias, M. L., Shroff, A., Hart, E. A., & Roulston, C. A. (2022). A randomized trial of online single-session interventions for adolescent depression during COVID-19. *Nature human behaviour*, 6(2), 258–268. <https://doi.org/10.1038/s41562-021-01235-0>
- Schleider, J. L., Mullarkey, M. C., Fox, K. R., Dobias, M. L., Shroff, A., Hart, E. A., & Roulston, C. A. (2021). A randomized trial of online single-session interventions for adolescent depression during COVID-19. *Nat Hum Behav*. <https://doi.org/10.1038/s41562-021-01235-0>
- Singh, S. P., Paul, M., Ford, T., Kramer, T., Weaver, T., McLaren, S., Hovish, K., Islam, Z., Belling, R., & White, S. (2010). Process, outcome and experience of transition from child to adult mental healthcare: multiperspective study. *The British journal of psychiatry : the journal of mental science*, 197(4), 305–312. <https://doi.org/10.1192/bjp.bp.109.075135>
- Skivington, K., Matthews, L., Simpson, S. A., Craig, P., Baird, J., Blazeby, J. M., ... & Moore, L. (2021). Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update. *Health technology assessment (Winchester, England)*, 25(57), 1.
- Stewart-Brown S, Tennant A, Tennant R, Platt S, Parkinson J, Weich S. Internal construct validity of the Warwick-Edinburgh mental well-being scale (WEMWBS): a Rasch analysis using data from the Scottish health education population survey. *Health Qual Life Outcomes*. 2009;1(7):1–8. doi: 10.1186/1477-7525-7-15.
- Taylor, M. E., Liu, M., Abelson, S., Eisenberg, D., Lipson, S. K., & Schueller, S. M. (2024). The Reach, Effectiveness, Adoption, Implementation, and Maintenance of Digital Mental Health Interventions for College Students: A Systematic Review. *Current psychiatry reports*, 26(12), 683–693. <https://doi.org/10.1007/s11920-024-01545-w>
- Thapar, A., Eyre, O., Patel, V., & Brent, D. (2022). Depression in young people. *Lancet (London, England)*, 400(10352), 617–631. [https://doi.org/10.1016/S0140-6736\(22\)01012-1](https://doi.org/10.1016/S0140-6736(22)01012-1)
- ten Have, M., de Graaf, R., Ormel, J., Vilagut, G., Kovess, V., Alonso, J., & ESEMED/MHEDEA 2000 Investigators. (2010). Are attitudes towards mental health help-seeking associated with service use? Results from the European Study of Epidemiology of Mental Disorders. *Social psychiatry and psychiatric epidemiology*, 45(2), 153-163.
- Tindall, L., Kerrigan, P., Li, J., Hayward, E., & Gega, L. (2024). Is behavioural activation an effective treatment for depression in children and adolescents? An updated systematic review and meta-analysis. *European child & adolescent psychiatry*, 33(12), 4133–4156. <https://doi.org/10.1007/s00787-024-02429-3>

Wood D, Crapnell T, Lau L, et al. Emerging Adulthood as a Critical Stage in the Life Course. 2017 Nov 21. In: Halfon N, Forrest CB, Lerner RM, et al., editors. Handbook of Life Course Health Development [Internet]. Cham (CH): Springer; 2018. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK543712/> doi: 10.1007/978-3-319-47143-3\_7

Yardley, L., Morrison, L., Bradbury, K., & Muller, I. (2015). The person-based approach to intervention development: application to digital health-related behavior change interventions. *Journal of medical Internet research*, 17(1), e4055.