

# Acceptability and feasibility of a serious game intervention for young people with adverse childhood experiences

<b>Submission date</b> 13/05/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 29/05/2024	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/08/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Adverse Childhood Experiences (ACEs) include various forms of early life stress, including abuse (verbal, sexual, or physical), neglect, and household challenges such as parental separation or incarceration. In particular, these experiences can be common in socio-economically deprived areas and can significantly impact mental and physical health. ACEs can lead to complex trauma symptoms, such as avoidance and difficulty regulating emotions, which can affect engagement in therapy and interventions. Recognising these challenges, innovative approaches such as game-based interventions are being explored. This study focuses on co-developing and assessing a serious game tailored for young people who often do not engage well with standard services, particularly those affected by ACEs. Specifically, this study aims to determine whether a co-designed, youth-informed game is an acceptable and feasible approach for these young individuals, and explore the specific mental health benefits of the game for adolescents with ACEs.

### Who can participate?

Young people between the ages of 12 to 24 years, who have experienced three or more types of ACEs.

### What does the study involve?

To test the serious game, this study will recruit young people aged 12-24 from diverse backgrounds, including LGBTQIA+, ethnic minorities, neurodivergent individuals, and marginalized groups such as refugees and travelers. Participants will come from various places including rural, coastal, and urban areas in England, and will have different educational and health service experiences. The feasibility and acceptability of the game will be assessed using surveys taken before and after the game is played, and three months later to see how it affects their mental health wellbeing. In-game data will also provide insight such as how long each play session lasts, choices made in the game, and parts where players stop playing. Participants will be interviewed at the end to explore the context where they played the game, the levels of support needed, elements of the intervention that are helpful or unhelpful, and experience of benefits and concerns.

What are the possible benefits and risks of participating?

It is hoped the game will help those who have experienced a wide range of unpleasant adversities and that it will be accessible to a broad range of young people. Possible benefits include improved mental health wellbeing, self-compassion and compassion to others with ACEs, and help-seeking behaviours. If at any point during the study, there is thought to be an immediate risk of serious harm to the participant, for example, if a participant scores highly on suicidal/risky behaviours, this will be discussed with the participant and inform the safeguarding team to make sure the participant stays safe. Only information that is relevant to the emergency will be shared.

Where is the study run from?

1. University of Oxford (UK)
2. Falmouth University (UK)

When is the study starting and how long is it expected to run for?

September 2021 to August 2025

Who is funding the study?

UK Research and Innovation (UKRI)

Who is the main contact?

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2. Dr Isabelle Butcher, isabelle.butcher@psych.ox.ac.uk
3. Harsimran Sansoy, harsimran.sansoy@psych.ox.ac.uk

### **Study website**

<https://www.attuneproject.com/>

## **Contact information**

### **Type(s)**

Principal Investigator

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**Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

312815

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

MR/W002183/1, IRAS 312815

## Study information

**Scientific Title**

Understanding mechanisms and mental health impacts of adverse childhood experiences to co-design preventive arts and digital interventions (ATTUNE) project

**Acronym**

ATTUNE

**Study objectives**

As this is a feasibility study no formal hypothesis testing will be undertaken.

This study explores the acceptability and feasibility of a serious game intervention co-designed with young people and investigates its impact on mental health wellbeing, compassion and help-seeking in young people with adverse childhood experiences.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

Approved 25/09/2023, West Midlands - Solihull Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; None provided; solihull.rec@hra.nhs.uk), ref: 23 /WM/0105

**Study design**

Non-randomized feasibility study with process evaluation

**Primary study design**

Interventional

**Secondary study design**

Non randomised study

**Study setting(s)**

Charity/Voluntary sector, Community, Home, Internet/virtual, School, University/medical school /dental school

**Study type(s)**

Prevention, Quality of life, Safety

## **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet.

## **Health condition(s) or problem(s) studied**

Promoting mental health wellbeing and help-seeking in young people with adverse childhood experiences

## **Interventions**

The acceptability and feasibility study will broadly follow MRC guidance on the evaluation of complex interventions.

The serious game intervention, co-designed with young people, includes a series of mini-games tailored to address different Adverse Childhood Experiences (ACEs). These mini-games focus on specific challenges such as coping with bereavement, poverty, gender dysphoria, and the challenges of being a young carer. Each game adopts a unique format to engage players effectively, some offering a virtual space where players can explore narratives and develop resilience to meet real-life challenges, some using a 2D side-scrolling format to navigate a dark forest, symbolising the journey of a young carer. The games integrate metaphors to address sensitive issues with both subtlety and empathy.

Questionnaires will be completed at the baseline of the serious game intervention, immediately post-intervention, and at a 3-month follow-up. Quantitative data will be collected and assess pre-post differences of mean scores and distributions on validated measures of wellbeing (Warwick Edinburgh Mental Wellbeing Scale-7 item suitable for YP (aged 15-21), post-traumatic symptoms (Revised Impact of Events Scale-13 items covering reexperiencing, avoidance, hyperarousal), anxiety (GAD-7), depression (PHQ-9), self-compassion (Neff Scale) and use of services and engagement with educational/social activities.

Where possible, the screening and all questionnaires will be conducted face-to-face with support from a trained researcher at the partner organisation, or online via Teams. In-person support will be available to those completing the questionnaires unless they have been screened as able to do this online. The young person will fill in the forms using a digital device provided (tablet or computer). When judged appropriate (e.g., for older adolescents), links to questionnaires will be sent via email and the game completed independently online.

In addition, a process evaluation will be undertaken with 20-40 young people, who participated in the evaluation, ensuring representation from those who had high, medium and low levels of engagement with the game, including those who did not engage with the intervention or dropped out (subject to consent to follow up). The process evaluation will assess qualitatively: the context of gameplay, levels of support needed, elements of the game intervention that were helpful or unhelpful, experiences and mechanisms of benefits and concerns.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Acceptability measured using interviews and the 22-item acceptability of health apps among adolescents (AHAA) scale adapted for this study at post-intervention
2. Feasibility on success in recruitment of diverse groups (age, gender, ethnicity, sexuality, rural/coastal/urban localities), use of the game (frequency, duration, at least 3-5 occasions over 1-2

months), retention in the study to the end, completion of outcome measures, reliability of delivery mechanisms (digital and remote), presence of sufficient support from intervention in-built elements and the location of delivery measured using study data and in-game data collected at the end of the study

3. Mental health wellbeing outcomes measured using the Short Warwick Edinburgh Mental Wellbeing Scale (7 items) at baseline, post-intervention, and 3-month follow-up

### **Secondary outcome measures**

The following secondary outcome measures will be assessed at baseline, post-intervention and 3-month follow-up:

1. Distress caused by traumatic events measured using the Revised Impact of Events Scale - 13 items
2. Anxiety symptoms measured using the Generalised Anxiety Disorder Assessment (GAD-7)
3. Depression symptoms measured using the Patient Health Questionnaire (PHQ-9)
4. Self-compassion measured using the Self-Compassion Scale for Youths (SCS-Y)
5. Service use measured using the Client Service Receipt Inventory (CSRI)

### **Overall study start date**

01/09/2021

### **Completion date**

31/08/2025

## **Eligibility**

### **Key inclusion criteria**

1. Having experienced more than three adverse childhood experiences (ACEs)
2. Between the age of 12-24 years

### **Participant type(s)**

Healthy volunteer, Learner/student, Service user

### **Age group**

Mixed

### **Lower age limit**

12 Years

### **Upper age limit**

24 Years

### **Sex**

Both

### **Target number of participants**

40

### **Total final enrolment**

35

**Key exclusion criteria**

Involvement in any other parts of the game co-design in this project

**Date of first enrolment**

01/06/2024

**Date of final enrolment**

15/05/2025

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre****University of Oxford**

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**Study participating centre****Falmouth University**

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**Sponsor information****Organisation**

University of Oxford

**Sponsor details**

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**Sponsor type**

University/education

**Website**

<https://www.ox.ac.uk/>

**ROR**

<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

UK Research and Innovation

**Alternative Name(s)**

UKRI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

Planned publication of study results in peer-reviewed journals. Dissemination will target academic, healthcare, education, social care, third sector and local government settings via knowledge exchange events, social media, accessible briefings, conference presentations and publications.

**Intention to publish date**

01/06/2025

**Individual participant data (IPD) sharing plan**



We would like to clarify that the ‘raw data’ or the individual-level data will not be shared, but anonymised survey data for analysis and transcripts/notes might be available upon request. More details below:

1. The name and email address of the investigator/body who should be contacted for access to the datasets: Kam Bhui (PI): kam.bhui@psych.ox.ac.uk
2. The type of data that will be shared: Anonymised survey data and transcripts/notes might be shared. We will remove or recode demographic variables and/or use small count suppression to protect participants’ privacy and prevent re-identification.
3. Timing for availability: All anonymised data will be archived for 10 years on the relevant Oxford network server following the end of the study. Please note that this is a UKRI MRC-funded project and the guidelines stipulated by the funder will be adhered to. The Medical Research Council states that the “aim for data-sharing is to maximise the lifetime value of research data assets for human health and to do so in a way that is timely, responsible, with as few restrictions as possible, and consistent with the law, regulations and recognised good practice.” The MRC expects that data must be retained for a minimum of 10 years after the study has been completed.
4. Whether consent from participants was required and obtained: Consent will be required and obtained.

**IPD sharing plan summary**  
Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol (preprint)</a>		29/12/2023	16/05/2024	No	No