ISRCTN75033471 https://doi.org/10.1186/ISRCTN75033471

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

Submission date
13/05/2024

Recruitment status
No longer recruiting

Registration date
29/05/2024

Overall study status
Ongoing

Last Edited
16/05/2024

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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?
1. Dr Zhuo Li, jo.li@psych.ox.ac.uk
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

Contact name
Prof Kamaldeep Bhui

ORCID ID
https://orcid.org/0000-0002-9205-2144

Contact details
Department of Psychiatry,
University of Oxford
Oxford
United Kingdom
OX3 7JX
None provided
kam.bhui@psych.ox.ac.uk

Type(s)
Scientific

Contact name
Dr Zhuo Li

ORCID ID
https://orcid.org/0000-0003-3324-096X

Contact details
Department of Psychiatry,
University of Oxford
Oxford
United Kingdom
OX3 7JX
None provided
jo.li@psych.ox.ac.uk

Type(s)
Scientific

Contact name
Dr Isabelle Butcher

ORCID ID
https://orcid.org/0000-0003-2915-8269

Contact details
Department of Psychiatry,
University of Oxford
Oxford
United Kingdom
OX3 7JX
None provided
isabelle.butcher@psych.ox.ac.uk

Type(s)
Public

Contact name
Ms Harsimran Sansoy

Contact details
Department of Psychiatry,
University of Oxford
Oxford
United Kingdom
OX3 7JX
None provided
harsimran.sansoy@psych.ox.ac.uk

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
01/08/2025

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

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
30/09/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Oxford
Department of Psychiatry, Warneford Hospital
Oxford
United Kingdom
OX3 7JX

Study participating centre
Falmouth University
Penryn Campus, Treliever Road
Penryn
United Kingdom
TR10 9FE

Sponsor information

Organisation
University of Oxford

Sponsor details
Research Governance, Ethics and Assurance Joint Research Office
Boundary Brook House
Churchill Drive
Headington
Oxford
England
United Kingdom
OX3 7GB
None provided
rgea.sponsor@admin.ox.ac.uk

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?
Protocol (preprint)		29/12/2023	16/05/2024	No	No