ISRCTN14772616 https://doi.org/10.1186/ISRCTN14772616

An online remote psychological intervention to sustain and promote people's wellbeing

Submission date
15/07/2021

Recruitment status
No longer recruiting

Registration date
16/07/2021

Overall study status
Completed

Last Edited
04/08/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The 'Psychology And yoU: Self-Enhancement programme' (PAUSE) programme aims to support and promote psychological well-being. It has been developed in the context of the COVID-19 pandemic, where effective and evidence-based remote interventions are needed. The PAUSE programme will provide users with valuable tools and skills that they may choose to implement in their daily lives, in order to foster and support positive mental well-being. The programme includes six modules: Well-being and Happiness; Healthy Body and Mind; Being Grateful and Savouring Life; Thought and Action; Strengthening Relationships; and Overcoming Challenges. The aim of this study is to find out whether people who engage with the PAUSE project will have increased psychological well-being after completing the 6-week programme, over a treatment-as-usual group of healthy individuals.

Who can participate?
Healthy volunteers aged over 18 years, recruited using media outlets, social media, and professional networking websites in Ireland

What does the study involve?
Participants are randomly allocated to either the PAUSE programme or a wait-list control group. Assessments are conducted before and after intervention, and at 6-weeks follow-up, each of which will take about 20 minutes. Following the 6-week period, participants in the waiting-list control group will be given access to the PAUSE programme.

What are the possible benefits and risks?
It is possible that a person's psychological well-being may improve over time as a result of taking part in this trial. The researchers do not anticipate any significant risks arising from taking part in this study.

Where is this study run from?
University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
May 2020 to September 2022

Who is funding this study?
Health Research Board (Ireland)

Who is the main contact for this study?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A remote self-directed psychological intervention for the public: the PAUSE project

Acronym
PAUSE

Study objectives
It is hypothesised that people who engage with the PAUSE project will have increased psychological well-being after completing the 6-week programme, over a treatment-as-usual group of healthy individuals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, University College Dublin Research Ethics Committee

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Quality of life

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Improving psychological well-being in the general public

Interventions
This study adopts a Groups X Time design with participants being randomly assigned to either an intervention or wait-list control group. Assessments are conducted before and after the intervention and at 6-weeks follow-up to evaluate the efficacy of the PAUSE programme among an Irish cohort. It will be explained to participants that there are three different assessment time points, each of which will take approximately 20 minutes (baseline, immediate follow-up, and 6 weeks post-intervention). The programme's modules will also be sequential, therefore a participant will not be able to engage with the next module until a previous module is complete, incorporating theoretical principles of gamification i.e., "You've unlocked Module 2". Following completion of the six modules, participants will complete the immediate post-intervention measures, and complete them again at 6 weeks. Following this 6-week period, the application will be fully available to the user should they wish to return to the programme at their own leisure. At this point, participants in the waiting-list control group will be given access to the PAUSE programme. Principal investigator involvement occurred with the design of this study, inclusive of authorship, with collaboration continuing throughout.

The PAUSE programme is a research-informed and evidence-based psychological intervention in which positive psychology exercises are used for self-development (Carr, 2019). The programme is remotely delivered through a smartphone app, with a range of strategies being used to enhance well-being and optimize mood management and self-regulation skills through six core modules: Well-being and Happiness; Healthy Body and Mind; Being Grateful and Savouring Life; Thought and Action; Strengthening Relationships; and Overcoming Challenges.

The PAUSE programme allows users to interact with module-specific content and to engage interactively with activities within 30–45-minute guided modules. These app delivered modules are similar in content and duration to clinical sessions. The PAUSE programme incorporates a series of exercises to be completed between module sessions, which can act as both a workbook and reflective practice. For ease of engagement, the app includes reminders, prompts, and notifications that support the completion of specific exercises. Notifications are automatically generated and are not sent if participants have completed exercises. Participants are also invited to rate their general mood and well-being prior to completing each exercise (1-10; where 10 equates to excellent) and again after. This provides immediate feedback on the impact of module-related exercises on well-being.

Randomisation will be a 2:1 experimental to control ratio with random sequence generation used to allocate participants. The groups will be blinded to the researcher conducting the statistical outcomes.

Intervention Type
Behavioural

Primary outcome measure
1. Subjective well-being will be measured using the World Health Organisation-5 wellbeing scale (WHO-5) at baseline, immediately following intervention (6 weeks later), and at follow-up (6 weeks thereafter)
2. Depression, Anxiety, and Stress will be measured using the Depression, Anxiety, Stress Scale (DASS-21) at baseline, immediately following intervention (6 weeks later), and at follow-up (6 weeks thereafter)
3. The Impact of Events Scale -Revised (IES-R) will be used to measure post-traumatic stress at the follow-up phase (12 weeks after beginning the intervention/treatment as usual)

Secondary outcome measures
1. The Brief Illness Perception Questionnaire (BIPQ) will assess cognitive and emotional appraisals of COVID-19 at baseline, immediately following intervention (6 weeks later), and at follow-up (6 weeks thereafter)
2. The Brief Cope Inventory will measure psychological coping styles at baseline, immediately following intervention (6 weeks later), and at follow-up (6 weeks thereafter)
3. The Posttraumatic growth inventory will measure psychological growth resulting from the COVID-19 pandemic at baseline, immediately following intervention (6 weeks later), and at follow-up (6 weeks thereafter)

Overall study start date
01/05/2020

Completion date
01/09/2022

Eligibility

Key inclusion criteria
1. Over the age of 18 years
2. Living in Ireland
3. Read an information leaflet and give consent prior to engaging with the programme
4. Have access to a technological device/smartphone for intervention purposes

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/09/2021

Date of final enrolment
01/02/2022

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
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Sponsor information

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University College Dublin

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Sponsor type
University/education

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ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Government

Funder Name
Health Research Board

Alternative Name(s)
Health Research Board, Ireland, An Bord Taighde Sláinte, HRB

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Ireland

Results and Publications

Publication and dissemination plan
The dissemination strategy will follow the Evidence-based model for the Transfer and Exchange of Research Knowledge (EMTReK) and study findings will be prepared in line with various formats (e.g. study newsletters, conferences/meetings) in order to meet the needs of different audiences. Targeted and timely dissemination activities are anticipated, and the team intends to disseminate research in an ongoing manner, throughout the lifetime of the project.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a publically available repository.
Numerical anonymised outcome data will be stored within the data repository to be sought from SpringerNature; data will be made available upon request to the Principal Investigator with no time or usage restrictions. Participants are informed and consent to this process. A link will be provided to the data repository when available.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	05/04/2021	04/08/2021	No	Yes