STUDY PROTOCOL

A remote self-directed psychological intervention for the public: The PAUSE programme protocol [version 1; peer review: awaiting peer review]

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Abstract

Background: This protocol outlines procedures for the development and evaluation of a remotely accessible intervention tool known as the '**P**sychology **A**nd yo**U: S**elf-**E**nhancement programme' (i.e., PAUSE programme). The PAUSE programme aims to support and promote psychological well-being using positive psychological concepts and principles. The programme has been developed in the context of the coronavirus disease 2019 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.

Methods: Participants will be recruited using media outlets, social media, and professional networking websites in Ireland. Those who choose to participate in this study will be asked to complete a set of measures at baseline, immediate follow-up, and six weeks post-intervention. This will allow for changes in subjective well-being scores

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Any reports and responses or comments on the article can be found at the end of the article.

to be analysed and interpreted over time. This study adopts a Groups x Time design, with participants being randomly assigned to either an intervention or wait-list control group. Ethical approval is currently under review at the host institution.
Dissemination: 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.
Registration: This RCT protocol is pre-results and has been registered with an international database resulting in an International Standard Randomised Controlled Trials Number (ISRCTN14772616)

Keywords
Positive Psychology, Remote Intervention, COVID-19, Psychological Distress, Therapeutics, Ireland, Public, Mental Health

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Introduction

The uncertainty of a developing global pandemic, resulting from the spread of a novel coronavirus known as coronavirus disease 2019 (COVID-19), elicits psychological responses which may present as greater psychological distress (Marazziti, 2020). Individual factors such as perceived vulnerability and/or anxiety proneness, either independent or accompanied by the implementation of public health measures such as containment strategies like lockdowns or quarantine, pose an acute threat to mental health (Asmundson & Taylor, 2020; Reynolds *et al.*, 2008; Smith *et al.,* 2020). As research examining outcomes and psychological responses resulting from COVID-19 continues to evolve, a consensus within the literature suggests that a proportion of the global population are experiencing notable increases in anxiety, stress, and depression symptomatology (Burke *et al.,* 2020; González-Sanguino *et al.,* 2020; Smith *et al.,* 2020; Wang *et al.,* 2020). As well as individual factors, symptoms of psychological distress may be heightened due to the associated risk with having an existing underlying medical condition, which is a negative prognostic factor in people who contract COVID-19 (Emami *et al.,* 2020; Özdin & Bayrak Özdin, 2020; Yu *et al.,* 2011). Furthermore, a perpetuating factor may also be the worry of the widespread societal and economic impact resulting from the pandemic (Guan *et al.,* 2020; Xiong *et al.,* 2020).

Psychological distress can negatively impact a wide variety of individuals. In the context of a global pandemic, there are especially vulnerable populations such as those with underlying health conditions, older aging adults, and frontline healthcare workers, who may be faced with particular psychological responses such as fear, insomnia, and anxiety (Emami *et al.,* 2020; Pappa *et al.,* 2020). Anxiety, depression, and other manifestations of psychological distress are known to present across the lifespan, and in the context of COVID-19 there becomes an increasing need for effective, accessible, and sustainable psychological support in this matter (Brooks *et al.,* 2020; Kelly, 2020; Liu *et al.,* 2012). Newly developed health and intervention-based services should not only consider targeting vulnerable populations, but must also be inclusive of the general public, with an ultimate goal being to support as many individuals as possible, in line with stepped models of care (Hao *et al.,* 2020; Xiong *et al.,* 2020).

In addition to individuals being predisposed to the negative effects of pandemic-related stressors, mandatory lockdown and self-isolation can reduce an individual's access to their typical coping strategies (e.g. attending indoor exercise clubs), and further inhibit interpersonal relationships (da Silva Lopes & Jaspal, 2020). To combat this, low-intensity techniques, such as savouring positivity through ordinary sensory behaviour and engaging in reflective daily practice, can help amplify positive emotions and foster psychological resilience (Yamaguchi *et al.,* 2020). In a meta-analysis of over 340 studies involving over 72,000 participants, Carr *et al.* (2020) found that positive psychological interventions, delivered both face-to-face and remotely, had a significant positive impact on well-being in both clinical and non-clinical samples. In this context, positive psychological interventions included, for example, setting valued goals, imagining one's best possible self, using signature strengths, savouring pleasures, finding flow, being grateful for positive experiences, developing optimism, strengthening relationships, practicing kindness, developing grit, being courageous, engaging in post-traumatic growth, and practicing forgiveness. Gratitude, joy, and comfort are but few of the positive emotions experienced when cultivating compassion and these emotions have been shown not only to maintain and improve mental health, but also to assist in the process of psychological recovery when an individual is confronted with intense distress (Yamaguchi *et al.,* 2020).

Prior to COVID-19, clinician-scientists have investigated the development and evaluation of remote telehealth supports for people experiencing psychological distress. At present, research supports the use of digitised and computerized mindfulness-based and compassionate mind-focused therapies, in which mindfulness practice and coping skills training are shown to be highly effective in alleviating negative psychological and psychiatric outcomes such as depression and paranoia (Braehler *et al.,* 2013; Chadwick *et al.,* 2016). In a systematic review conducted to evaluate the efficacy of computerized cognitive behaviour therapy (cCBT), Kaltenthaler *et al.* (2004) revealed that cCBT often showed equivalent outcomes to traditional CBT and more effective outcomes than treatment as usual. Typically, traditional models of therapy reach a small proportion of individuals due to a number of organisational and economic factors (such as being placed on long waiting lists), and within the context of COVID-19 the implementation and evaluation of remote psychological supports continue to be imperative (Kaltenthaler *et al.,* 2004). Currently, and following the COVID-19 pandemic, there is need for low-intensity mental health care strategies from a positive psychological perspective to foster compassion, gratitude, and joy, and to develop a creative solution to address the demand for a remote tool which can support psychoeducation, develop and foster positive emotions, and create active routines of engagement that can be used during and after the COVID-19 pandemic.

This research aims to evaluate a remote, low-intensity, self-directed, psychological support intervention known as the "**P**sychology **A**nd yo**U**: **S**elf-**E**nhancement programme" (PAUSE programme). This intervention proposes to fulfil the need for a remotely accessible online tool that will help support psychological well-being through an integrative psychological framework which aims to improve psychological well-being.

Protocol

The PAUSE programme is registered with an international database resulting in an International Standard Randomised Controlled Trials Number (ISRCTN14772616). This 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 (i.e. through Google Play Store and Apple Store), 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. A detailed breakdown of the core intervention structure and content can be seen in supporting Table 1.

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

Table 1. Overview of the PAUSE programme.

	Session topic	Intervention/module	Psychoeducation	Skills/actions
1	Well-being and Happiness	Positive Psychology	• Overview of Positive Psychology and current literature on happiness/wellbeing • Broad and Build theory • Fight/Flight/Freeze response	
		Highly Valued Goals	• Characteristics of highly valued goals • Setting and monitoring goals	➢ Identify your highly valued goals
		Personal Strengths	• Research on character strengths and associations with wellbeing	➢ Identify your personal strengths and use them
2	Healthy Body and Mind	Physical Exercise	• Links between physical activity and well-being. • The physical and psychological benefits of regular exercise. • Planning an exercise schedule. • The importance of diet and sleep.	➢ Create an exercise schedule/log
		Meditation Relaxation	• Forms of meditation and clinical use. • What is mindfulness and how to be consistent with mindfulness meditation practice.	➢ Breath and body exercise
			• Brief description of progressive muscular relaxation (PMR) and why it is used.	➢ Full guided PMR exercise
3	Being Grateful and Savouring Life	Savouring and Gratitude	• Description and information on both concepts • Defining state versus trait gratitude • How gratitude can impact and increase well-being	➢ Savouring exercise = relishing ordinary activities. ➢ Gratitude Jar
4	Thought and Action	Thinking Patterns	• Optimistic vs pessimistic thinking • Thinking Traps	➢ ABC(DE) Analysis
		Problem Solving	• Links to problem solving and well-being	➢ Problem solving
5	Strengthening Relationships	Compassion Building	• Links between relationships and well-being • Overview of Compassion Focused Therapy • Putting compassion into action	➢ Compassion meditation practice
		Couple Relationships	• Love 2.0 – extension of the Broad and Build Theory • Sound Relationship House theory	➢ Active listening skills
		Parenting Skills (optional module)	• Parenting styles • Attachment styles • Relationship building • Managing difficult behaviour • Self-care	➢ Non-critical speaking skills

	Session topic	Intervention/module	Psychoeducation	Skills/actions
6	Overcoming Challenges	Striving for Perfection	• Defining Grit and its presentation as a character trait • Discuss perfectionism and how it may become problematic	➢ ABC(DE) analysis of problematic perfectionist moments
		Monitoring fear/anxiety and building courage	• Information regarding current research on courage • The multidimensional nature of fear and anxiety (with reference to fight/flight/freeze discussed in part 1)	➢ Courageous steps to overcoming fear and/or anxiety (exposure through imagining or writing)
		Anger and Forgiveness	• A model of assertiveness and anger • Thinking traps associated with anger • Benefits of forgiveness • *REACH* – Pyramid of forgiveness	➢ Reflect: learn your own anger pattern/triggers/risk factors
	Summary		Brief summary of each module and final words	

Note: Overview of Intervention Features adapted from Alan Carr's *'Positive Psychology and You: A Self-Development Guide'*

a workbook and reflective practice. For ease of engagement, the app includes reminders, prompts, and notifications which support 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.

Participants

Participants will self-select to engage in the PAUSE programme evaluation study which will include online assessment and intervention. Study information will be disseminated in collaboration with the University College Dublin's (UCD) School of Psychology, shared on social media, and via news media platforms. Participants who gave consent in a previous study (Burke *et al.,* 2020) to be contacted for future research related to psychological well-being and COVID-19 will also be invited to participate in the current study by email. With guided instruction, participants will create a Unique Identification Code which only they will know. This allows the code to be regenerated easily by the individual, should they have difficulty recalling their own code.

Participants will have the right to withdraw from the study at any time should they wish to do so. This can be done by writing to the team via email and informing them of the decision to withdraw. To do this, we require the participant to inform the research team of their unique ID code, so that they can remove all data associated with it. Participants do not have to justify their reason for withdrawal, and it is not required that they complete all questionnaires or the full programme before withdrawing; they can do so at any point. If interested in partaking in the study, participants will receive an information sheet with a contact email address specific to the PAUSE research team.

In order to fulfil inclusion criteria, participants must be over the age of 18, living in Ireland, and are required to read an information leaflet and to give consent prior to engaging with the programme. Participants must also have access to a technological device/smartphone for intervention purposes. Participants will be required to confirm their study eligibility and consent on Qualtrics prior to completing the questionnaires and proceeding. Anyone who does not meet the inclusion criteria will be excluded from the study.

Sample size calculation

An a priori power analysis was conducted with G*Power 3 indicating for one-tailed statistical tests with p-values of 0.05 and power values of 0.80 to detect moderate differences (d=0.5), 26 participants are required per group.

Design

This study adopts a Groups x Time design with participants being randomly assigned to either an intervention or wait-list control group. The principal investigator will allocate participants to a group using random sequence generation (i.e. using computer generated random numbers), and for every participant in the experimental group, there will be an equal control participant (i.e. 1:1 allocation ratio). Participants' Unique Identification Code will be used in the process of random group allocation to ensure the blinding of participants from the research team both before and after assignment. Assessments for both groups are conducted before and after intervention, and at six-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 six-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

principals 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 six weeks. Following this six 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.

Measures

Pre- and post-intervention and follow-up assessment data will be collected using the survey software, Qualtrics. This allows participants to enter their data anonymously and remotely. Unique Identification Codes will further be used to link participants' pre- and post-intervention and follow-up assessment data. Demographic information regarding gender, age, marital status, family composition, socio-economic status, and general health, will be collected through Qualtrics and will act as confounding variables for analysis. Validated self-report measures used in clinical practice will be employed with questions pertaining to participants' own well-being, measures of event-specific trauma and specific measures relating to COVID-19. The World Health Organization Well-Being Index (WHO-5), the Depression, Anxiety, and Stress Scales (DASS-21), and the Impact of Event Scale - Revised and the State Anxiety Scale (IES-R) are primary outcomes. The Brief Illness Perceptions Questionnaire (BIPQ), the Brief Coping Orientation to Problem Experienced Inventory (Brief COPE Inventory), and the Post-traumatic Growth Inventory are secondary outcome measures. Table 2 outlines the psychometrics and their timelines in detail, which focus on wellbeing, coping, stress, trauma, and post-traumatic growth. Following completion of the baseline assessment, participants will be loaded onboard the platform, and invited to use their Qualtrics credentials to log-in to the PAUSE programme.

The WHO-5 is a short, self-administered scale designed to measure levels of subjective well-being. It has been shown to have satisfactory psychometric properties among various clinical and non-clinical samples (Topp *et al.,* 2015). It has further been demonstrated to have high internal consistency with a Cronbach's alpha of 0.91 (Lowe *et al.,* 2004).

The DASS-21 yields scores for depression, anxiety and stress, which are categorised into Normal, Mild, Moderate, Severe, or Extremely Severe. The reliability of the DASS-21 was considered acceptable (Cicchetti, 1994) and has shown "good" Cronbach's alpha values of 0.81 and 0.89 for the depression and anxiety subscales, respectively (Burke *et al.,* 2020). The alpha value for the stress subscale was considered "fair" (Cicchetti, 1994) with a value of 0.78 (Burke *et al.,* 2020).

The IES-R is a 22-item measure commonly used to measure post-traumatic stress following a prespecified traumatic event, with three subscales relating to Intrusion, Avoidance and Hyperarousal. Internal consistency was high among the total and subscale scores. The total scale had a Cronbach's alpha value of 0.95, with the Intrusion, Avoidance and Hyperarousal subscales yielding alpha values of 0.92, 0.85 and 0.91, respectively (Rash *et al.,* 2008).

The BIPQ assesses the cognitive and emotional representations of illness. For this study, the "Cognitive Perceptions" subscale was adapted for COVID-19, which asks about the effect of COVID-19 on life (item 1); perceived duration of COVID-19 (item 2); control over COVID-19 (item 3); beliefs about the effectiveness of treatment for COVID-19 (item 4); and experience of COVID-19 symptoms (item 5). A single item was added to the measure in order to capture people's understanding

Table 2. Overview of psychometrics to be administered at baseline, immediate follow-up, and six weeks post intervention.

Outcome		Instrument	T1	T2	T3
(a)	Demographics	Demographic questionnaire	☐		
	Effect of the COVID-19	Effects of COVID-19 Questionnaire (ECQ)	☐	☐	☐
(b)	Wellbeing	World Health Organization Well-Being Index (WHO-5)	☐	☐	☐
	Depression and Anxiety	Depression, Anxiety, and Stress Scales (DASS-21)	☐	☐	☐
	Trauma Symptoms	Impact of Event Scale - Revised (IES-R)	☐	☐	☐
(c)	Illness Perception	Brief Illness Perception Questionnaire (BIPQ)	☐	☐	☐
	Coping	Brief COPE Inventory	☐	☐	☐
	Post-traumatic Growth	Post-traumatic Growth Inventory			☐

Note. (a): sociodemographic; (b): primary outcomes; (c); secondary outcomes; DASS-21: (Lovibond & Lovibond, 1995); Brief COPE: (Carver, 1997); BIPQ: (Broadbent *et al.,* 2006); ECQ (Burke *et al.,* 2020); IES-R: (Weiss, 2007); WHO-5: (Topp *et al.,* 2015). T1 = baseline; T2= immediate post-intervention; T3= six week follow-up.

of COVID-19 (item 6). Items 1–5 are summed to give a total score for the "Cognitive Perceptions" scale. High BIPQ scores reflect negative perceptions of COVID-19. The reliability of the BIPQ has been shown to have a "good" Cronbach's alpha value of 0.85 (Burke *et al.,* 2020; Cicchetti, 1994).

The Brief COPE Inventory consists of 28 items organised into four subscales: Active Avoidance Coping, Problem-Focused Coping, Emotional Focused Coping and Positive Coping. Carver (1997) showed the Brief COPE to have a complex factor structure, with nine factors accounting for 72.4% of the variance. COPE scales generally exhibit strong convergent and discriminant validity in that they correlate with theoretically related scales (Meyer, 2001). The COPE scales are not strongly correlated with social desirability, which further demonstrates their validity (Carver *et al.,* 1989).

The Post Traumatic Growth Inventory is a 21 item scale that was developed to measure the positive changes experienced by an individual in the aftermath of stressful events. It has five subscales including New Possibilities, Relating to Others, Personal Strength, Appreciation of Life, and Spiritual Change. It's been validated among numerous populations and has been shown to have an overall high level of internal consistency (Cronbach's alpha = 0.87; Cadell *et al.,* 2015).

Data analysis

All data will be analysed using IBM SPSS Version 26 statistical software. An intent-to-treat and treatment completers analysis, i.e. those who complete the intervention and complete the 'Time 2' measures, will be performed. A 2 X 3, Groups × Time Multivariate Analysis of Variance (MANOVA) will be conducted, followed by ANOVAs and tests of simple effects to investigate the effects of group membership and time on dependent variables. In this design there will be two groups (intervention and control), and three levels of time (pre-intervention, post-intervention, and follow-up). Improvements in the intervention group and the absence of such improvement in the control group will be detected by significant Groups × Time interactions. The extent of these differences will be assessed by calculating effect sizes. Directly observed effects sizes will be reported, with categorisation into small/medium/large in line with Cohen's recommendations (Cohen, 1992). Improvement rates will be calculated for scales with clinical cut-offs i.e. DASS-21. Participants who score above cut-offs at Time 1, and below at Time 2 or 3 will be classified as clinically improved, with statistical significance assessed using chi square tests. Individual reliable change indices (RCI; Jacobson & Truax, 1991) from pre- to post-intervention, and from pre-intervention to follow-up, will be calculated for each participant. The significance of group differences in rates of reliable change will be assessed with chi square tests.

Ethics

Ethical approval for the current study has been sought from the host institution University College Dublin. Participants will be made aware that while completing questionnaires, difficult or upsetting feelings or thoughts may arise if they are finding the COVID-19 crisis particularly stressful. While our intervention is aimed at reducing psychological distress, we will provide additional information regarding clinically routine support and care pathways that participants are encouraged to access should they become distressed (e.g. national mental health charities and helplines). This care pathway and risk assessment is in line with many research projects.

Data management and dissemination

All data arising from this research project will be confidential to the research team, with data files and datasets being secured using a password that only the research team will know. Participants will create a Unique Identification Code which only they will know. This code will be used to link their data over three time points, and to the PAUSE programme app. Data provided on the Qualtrics platform will be stored on this platform and then deleted in 10 years' time by the Principal Investigator in line with national and international data protection laws. De-identified numerical data from assessment protocols will be archived on secured systems and in electronic data files for subsequent analysis by the research team or other investigators. The SPIRIT checklist, study materials, and dataset containing de-identified data will be uploaded to the Open Science Framework platform with no restrictions regarding reuse or reanalysis

In addition to dissemination through the HRB Open Research platform and UCD-related channels (i.e., public engagement, newsletters, and meetings), dissemination will be achieved through talks, conferences, social media, workshops, and research publications. This study proposes to follow the Evidence-based model for the Transfer and Exchange of Research Knowledge (EMTReK; developed at UCD), which highlights key elements for consideration to ensure knowledge transfer and dissemination activities are appropriate and provide a framework to evaluate their impact. In the dissemination plan, the research team carefully considers the messages to be transferred, the stakeholders, and the specific processes by which transfer will be achieved i.e., publication, talks, events, social media, press release etc. Key practical operational elements of these components will be considered, while recognising that multiple types of messages are important and the need to be aware of different processes when communicating with different stakeholders including the public. Echoing this, the use of diverse activities as part of our dissemination process will not solely focus on traditional methods such as academic dissemination. We consider the importance of targeted and timely dissemination activities. Rather than planning for dissemination at the end of this project, we intend to disseminate our research in an ongoing manner across the lifetime of the project, with immediate effect. Taking the above into account, our primary outputs for dissemination aim to include:

- media coverage and press releases
- research and executive summary documents
- online/PDF: flyers, posters, brochures and research briefs

- policy briefs
- study newsletters
- community agency publications and websites
- events, seminars, conferences, community meetings

Study status
This study has not yet commenced data collection. It is anticipated that data collection will begin in summer/autumn 2021.

Conclusion
The PAUSE programme is not specifically developed to alleviate COVID-19 related stressors, but rather it is designed within the context of a pandemic and in acknowledgment of the need for a remotely accessible psychological support in times where access to in-person treatments is reduced. As such, if effective, the programme itself has many future potential applications for members of the public, or those specifically on waiting-lists for support who may benefit from accessing evidence-informed psychological supports remotely, at their own pace, and at a time which is convenient to them and their context. The programme has been adapted from '*Positive Psychology and You: A Self-Development Guide'* (Carr, 2019), which promotes self-development in a flexible manner whereby readers are encouraged to work through the book at their own pace. The PAUSE programme will promote a similar method of user engagement and data gathered from participants will be analysed in an ongoing manner. In conclusion, the PAUSE programme has been created with the intention of promoting and supporting psychological well-being, and is timely in the integration of positive psychology frameworks and remote intervention deployment.

Data availability
Underlying data
No data are associated with this article.

Reporting guidelines
Open Science Framework: SPIRIT checklist for 'A remote self-directed psychological intervention for the public: The PAUSE programme protocol'. https://doi.org/10.17605/OSF.IO/8HSY2

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