Evaluation of self-initiated humour protocol

Submission date 03/03/2025	Recruitment status Recruiting	[X] Prospectively registered
		∐ Protocol
Registration date	Overall study status	Statistical analysis plan
04/03/2025	Ongoing	☐ Results
Last Edited	5 5	Individual participant data
13/05/2025		[X] Record updated in last year

Plain English summary of protocol

Background and study aims

We have developed the set of rule-based Self-Initiated Humour Protocol (SIHP) - derived and expanded from the Self-Attachment Technique (SAT) - for trying to learn to laugh in a non-hostile manner in a wide variety of contexts to increase positive emotions and moods, to reduce negative emotions and moods, and to enhance memory and cognitive abilities. As the name implies, rather than waiting for jokes, you initiate this humour protocol yourself and then use them to laugh.

SIHP uses the five main theories of laughter, which explain why and under what circumstance we laugh, to formulate a set of simple rules that can be easily learned and practised to be able to see the funny side of almost everything in life and develop a sense of humour. In a pilot 8-week SIHP study in 2023, the participants felt an improvement in their well-being, as well as an increase in their use of self-enhancing laughter, and increased ability to regulate their emotions and to solve problems after the daily practice of the exercises.

The aim of our current study is to evaluate the performance of SIHP where you learn this protocol in eight weekly sessions between 20-45 minutes and practice for 20 minutes each day.

Who can participate?

All healthy adults, based in Europe, Africa, Asia, North, South and Central America, aged 18-70 years who speak fluent English, have no current psychiatric illness or drug or alcohol addiction, and are not simultaneously starting any other type of psychological therapy during the 8-week course of SIHP and who can commit the required daily time for practising SIHP for a total of 20 minutes a day can volunteer to take part in this study (any psychological intervention that you have already been doing and are working for them can continue).

What does the study involve?

If you decide to take part and have completed the consent form, you will be asked to fill in a demographic questionnaire and two self-rating health questionnaires to measure your depression and anxiety. All questionnaires will be organized using the Qualtrics platform. If the questionnaires indicate that you are at risk of severe levels of clinical depression and/or anxiety, we will advise you to go to your GP or seek help from a mental health charity like Mind (https://www.mind.org.uk). If you meet all the inclusion and exclusion criteria, then you would be eligible to be selected for our study on a first come first serve basis. Based on the results of the screening process, if you are not selected to participate in the study, we will consider your status as not participating in the study and your data will be deleted accordingly. Any data collected

from you during the study will be pseudonymised and stored securely at Imperial College London, accessible only to members of the study team. You are free to withdraw from the study at any time by informing the members of the study team in writing via email, your data will be deleted accordingly.

If you are selected for the study, you will be able to use your unique study participant ID number as access credentials to our online platform. You will be randomly assigned to one of two cohorts, who will undertake the protocol at different times to manage the load on our investigation team. You will be required to complete the study's measurement questionnaires at the start of the program, immediately before the start of your intervention phase (which may be the same time as the program starts depending on your group assignment), immediately after the end of your intervention, and at 3-months after the end of the intervention. Questionnaires should take no more than 20-30 minutes total to complete at each phase. Each week as you are undertaking the protocol, you are required to watch a prerecorded presentation (between 20-45) minutes) by Abbas Edalat of the new SIHP exercises to be undertaken for the following week. You will be required to individually practice the SIHP exercises described in the presentation in the following week for a total of 20 minutes a day with the support of the digital platform. You will also be asked to fill out a simple diary on the digital platform to describe the experience you have during the daily practice of the protocol in each session. Personal diary entries will not be published nor accessible to other participants and will be used to ensure compliance with the protocol.

In the first 2 weeks you practise daily the core of the self-attachment technique by creating a compassionate and affectional bonding with your childhood self. For this you would be interacting with a childhood avatar, using a virtual environment, which will be created from your childhood photos of your choosing. Then in the subsequent 6 weeks, you will daily interact with a chatbot which coaches you to practise the self-initiated humour protocol exercises. Before the protocol, on its completion at 8 weeks and in a 3-month follow-up, you will fill out eight short questionnaires via the online Qualtrics platform to evaluate your well-being.

The chatbot will be accessible to you via a web application and is designed to aid you during the intervention by recommending and guiding you through practising exercises. The chatbot will begin a conversation by asking how you are feeling/what's been going on and will classify your emotional state from the response. In a positive emotional context, the chatbot recommends exercises that are designed to enhance positive emotions. In a negative emotional context (i.e., you are feeling 'sad' or 'anxious'), the chatbot will recommend appropriate exercises to you depending on their circumstances that are aimed to aid you in regulating negative emotions. You will always have the option to select and practise a specific exercise if you would like to. The chatbot will encourage you to practise the exercises at your own pace. Conversations with the chatbot will be pseudonymised and stored securely on Imperial College London servers to aid future efforts to improve the chatbot. In line with other personal data we store, this will be accessible only to members of the study team.

What are the possible benefits and risks of participating?

We cannot promise the study will help you but the information we get might help improve the protocol for enhancing positive affects in healthy individuals and help us develop a chatbot for learning to laugh. In the eight weeks, you will learn SIHP which, as shown in our previous pilot study, can help you to maximise your positive affects and minimize your negative affects at the time of stress in life. This may enhance your wellbeing and your cognitive abilities and empower you in your personal life and work.

The main issue is that taking part in the study will demand 20 minutes of your time in total every day for 8 weeks, in addition to watching a weekly prerecorded presentation between 20-45 minutes long and completing questionnaires for up to 30 minutes at 3 predetermined points over 5 months, which is a significant commitment. This means you need to dedicate yourself to a new learning task that initially you may find challenging. In fact, you may initially find practising

the protocol a little difficult since it may take you some time to get used to it. In principle, there's a slight possibility that you may experience psychological discomfort or distress while engaging in the SIHP protocol, particularly when addressing sensitive emotions or memories. In those instances, we will implement the distress protocol. Two clinicians, who are members of the investigation team, will be available in such instances to provide additional support and guidance if necessary.

Where is the study run from? Imperial College London (UK)

When is the study starting and how long is it expected to run for? July 2024 to October 2026

Who is funding the study? Empowered Human Foundation (UK)

Who is the main contact?

Prof. Abbas Edalat, a.edalat@imperial.ac.uk

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

Prof Abbas Edalat

ORCID ID

https://orcid.org/0000-0002-6211-1991

Contact details

Department of Computing 180 Queen's Gate London United Kingdom SW7 2RH +44 (0)2075948245 ae@ic.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Study information

Scientific Title

A randomised control trial to evaluate the efficacy of digital self-initiated humour protocol on sub-clinical population

Acronym

SIHP25

Study objectives

The Self-Initiated Humour Protocol (SIHP) intervention is efficacious in enhancing emotional wellbeing among adults in the subclinical population.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 03/02/2025, Imperial College Research Ethics Committee (ICREC) (Level 5, Sherfield Building South Kensington Campus Imperial College London, London, SW7 2AZ, United Kingdom; +44 (0)2075949456; rgitcoordinator@imperial.ac.uk), ref: 6962282

Study design

Single-centre interventional single-blinded waitlist randomized control trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

Study type(s)

Efficacy

Participant information sheet

https://humandevelopment.doc.ic.ac.uk/SIHP25/participant-information-sheet.pdf

Health condition(s) or problem(s) studied

Emotional well-being

Interventions

Pre-Intervention Phase:

We will begin with organising a Q&A session for potential volunteers to learn more about the study. Interested volunteers can submit their interest by completing the Trial consent form, after which they will be given three questionnaires for screening purposes. If participants do not satisfy the inclusion & exclusion criteria, they are not eligible to participate in the study, as such

they are not considered for the study and their personal data will deleted as appropriate. Participants will be informed that they were not selected due to the inclusion & exclusion criteria, in the event that this was due to their levels of anxiety and depression, they will be advised to seek assistance from mental health professionals and given links to relevant mental health charities (i.e. Mind https://www.mind.org.uk/ in the UK). Just before the intervention starts, participants will undergo baseline measurements to establish their initial levels of depression, anxiety, self-compassion, well-being, psychological capital, and emotion regulation. Then they will be introduced to the digital platform through tutorials to learn how to use it and be prepared for the intervention.

Participants will be randomised into two groups, the experimental group and the waiting list control group. Randomisation will be conducted by randomly ordering the list of participant IDs, with the two halves composed of different lists. We follow other works on compassion-based interventions (https://doi.org/10.1016/j.beth.2017.06.003) in using a waitlist as control to compare our intervention against. For the purposes of a single-blind study, participants will not be made aware of which group they belong to, both groups will be exposed to the intervention, with the second group receiving it at the conclusion of the first group's intervention phase, participants will be informed of this ordering. To maintain the single-blind nature of the RCT, we will inform the second group that this partitioning is to reduce the load on the investigation team. The experimental group will be provided with the 8-week Self-Initiated Humour Protocol (SIHP) intervention, whereas the control will enter an 8-week waiting period without any intervention. This waiting period serves to control for the potential effects of time on the measured outcomes. After the 8-week waiting period, the waiting list group will be offered the intervention.

Intervention Phase:

The intervention will be delivered through the digital SIHP platform and consists of eight video recordings of Prof. Abbas Edalat providing detailed instructions on the SIHP protocol and guiding participants through daily practice of SIHP exercises. The participants would individually practice the SIHP exercises, for at least 20 minutes a day during the eight weeks of the intervention.

Post-Intervention Phase

At the immediate conclusion of the 8-week intervention, participants will complete the full set of evaluation questionnaires as per pre-intervention. This will be repeated exactly 3 months after the conclusion of the intervention to form the 3-month follow-up results. Participants will be asked at this stage to complete the one-time platform evaluation questionnaires aimed at evaluating the chatbot, virtual environment and digital web platform they used during the study.

For each outcome we first test the difference between pre-intervention and post-intervention results for normality (Shapiro-Wilk) - If normality is not satisfied, we conduct the Wilcoxon signed-rank test for statistical significance (p < 0.05) and calculate the Matched-pairs rank-biserial correlation (r) as a measure of effect size. Otherwise, we perform a two-way ANOVA test for significance and use Cohen's d (d) as a measure of effect size.

SIHP protocol

In the first 2 weeks of the intervention, participants will practise the exercises using their childhood avatars, created from their childhood photos. This is a subset of the exercises in Study 21IC7351, which has now finished with promising results. In these two weeks, the participants make a compassionate connection and an affectional bonding with their childhood self and enhance their positive emotions by singing their favourite affectionate jolly song. They also externalise their negative emotions to their childhood avatars animated in the corresponding

emotions and then comfort their childhood self with loud verbal reassurance and a face/neck self-massage. A summary of those exercises is given below:

Visualising the child: Look at your most and least favourite childhood photos and the childhood avatar with different emotions, and use your power of imagination to interact with your childhood self.

Establish a compassionate connection with your childhood self: Focusing attention on your photos and avatar that you can animate into any of the seven basic emotions (happy, sad, angry, fearful, disgusted, surprised, neutral).

Affectional bond with the child: Use your favourite song, that expresses compassion and affection for your childhood self, to create a passionate and loving bond with your childhood self by repeatedly reciting the song while looking at your favourite photo and happy avatar.

Commitment to the child: Vocalise your love and commitment to re-raise your childhood self to enhanced social and emotional maturity.

Compassionate role model: Finding a secondary attachment object for the child from past experiences.

Joyful Love for the child: Maintain a loving relationship with the child by singing to/dancing with them. Joyful bonding with Nature.

Putting the happy childhood photo as the background on your mobile phone and trying to project/imagine this image on objects in your viewpoint around you.

Overcoming current or recent negative emotions: recall and project negative emotions arising from current or past events onto the childhood self, comfort the child.

In the subsequent six weeks, participants will practise the protocol using the laughter chatbot, evaluated in Study 22IC7536. They will also write a short note on their experience in their personal diary. A summary of those exercises is given below:

Playful mind: practice being more flexible and playful about your beliefs and thoughts. Playful face: loosen up muscles around mouth and eyes and sing your favourite jolly songs to simulate and encourage spontaneity.

Self-glory: after any mundane task, such as dishwashing or shopping, give yourself a smile/laugh as a victory gesture

Incongruous world: be cognizant of any contrast, incongruity, inconsistency, or discrepancy out there, using them to laugh

Incongruous self: be cognizant of any contrast, incongruity or discrepancy in your own inner world and thoughts, using them to laugh

Self/world incongruity: be cognizant of any contrast between reality and your expectation, using them to laugh

Contrasting views: stare at the well-known gestalt vase until your perception changes and laugh when this change of perception takes place

Your laughter brand: create our own form of laughter by repeating one of the following sounds with a specific vowel and turning it into laughter: ah, ah, ah, ah, ... eh, eh, eh, eh, ... oh, oh, oh, ... ih, ih, ih, ih, ih, ih, ...

Feigning laughter: as a mind exercise, simulate laughter without any humorous context Self-laughter: laugh at your errors, mistakes, blunders, mismanagement, and setbacks, all as unexpected events with Charlie Chaplin's perspective doctrine of laughter in mind.

SIHP platform

The objective of this project is to develop a web-based platform to facilitate the SIHP intervention. The choice of a web-based platform ensures significant flexibility and independence from the operating system, making it accessible to a broader audience. Development of the platform will involve participants from previous studies, whose experience and suggestions will inform the design of the platform. The web platform will encompass the following key components.

SIHP Study Dashboard

Section of the platform to provide comprehensive information about SIHP protocol and access to pre-recorded presentations that introduce SIHP exercises. Questionnaires used for the study can be accessed via the platform. Users can keep their personal diary.

LLM-Based SIHP Virtual Coach (Chatbot)

Users can interact with a web-based, LLM-powered (i.e. Meta Llama3) SIHP virtual coach that aims to guide the user through practising SIHP exercises. The chatbot will recognise the user's emotion through conversation and recommend appropriate SIHP exercises, particularly if the user's emotion is negative. In the case of disclosure of suicidal ideation or similar scenarios, the chatbot should direct the participant towards support in line with our distress protocol.

Virtual Environment with Personalised Child Avatar

A virtual environment has been created specifically for this study that includes the customised avatar of the user based on their childhood photo. An embedded editor, powered by AvatarSDK's Metaperson Creator (https://docs.metaperson.avatarsdk.com/js_api), allows the creation and customization of the avatar, including changes to clothes, hairstyles, facial features, and body proportions. Once the customisation is complete, the avatar can be saved and fetched onto a virtual scene.

The avatar can display various emotions through corresponding facial expressions and animations, selectable via buttons (emotions include happy, sad, angry, fearful, disgusted, surprised, and neutral). Users can select the emotion that is displayed on the child avatar and then practice the SIHP protocol. They can also change any emotion on the avatar to the happy emotion by staring at the avatar; prolonged staring would make the avatar start to dance with the participant's favourite jolly song.

Q&A Section & Tutorial

A section of the webpage will list frequently asked questions to help users navigate the platform and troubleshoot common issues, reducing operational overhead for the platform support team. Prerecorded tutorials can help the user learn to interact with the digital platform's features. Users will have the option to contact investigators for further inquiries and support.

Intervention Type

Behavioural

Primary outcome measure

Wellbeing measured using the PERMA Profiler immediately prior to the intervention (groups 1 & 2), at 8 weeks (groups 1 & 2), 16 weeks (group 2), 24 weeks (group 2), 30 weeks (group 1), 38 weeks (group 2)

Secondary outcome measures

Measured immediately prior to the intervention (groups 1 & 2), at 8 weeks (groups 1 & 2), 16 weeks (group 2), 24 weeks (group 2), 30 weeks (group 1), 38 weeks (group 2):

- 1. Depression measured using the Patient Health Questionnaire-9 (PHQ-9)
- 2. Anxiety measured using the Generalised Anxiety Disorder-7 (GAD-7)
- 3. Self-compassion measured using the Sussex-Oxford Compassion for the Self Scale (SOCS-S)
- 4. Compassion measured using the Compassion Scale
- 5. Emotional self-regulation measured using the Emotion Regulation Questionnaire (ERQ)
- 6. Humour styles measured using the Humour Styles Questionnaire (HSQ)
- 7. Psychological capital measured using the Revised Compound Psychological Capital scale (CPC-12R)

Overall study start date

08/07/2024

Completion date

10/10/2026

Eligibility

Key inclusion criteria

- 1. Adults (aged 18 years and above)
- 2. Fluent in the English language
- 3. Have a good-quality childhood photo
- 4. PHQ-9 score less than 15 (excluding moderately severe depression and anxiety) and above 4.
- 5. GAD-7 score less than 15 (excluding moderately severe depression and anxiety) and above 4

Participant type(s)

Population

Age group

Adult

Lower age limit

18 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

80

Key exclusion criteria

- 1. Any history of organic brain disease such as dementia, MS and Parkinson's disease
- 2. Substance abuse (drug or alcohol)
- 3. Have recently started (within 3 months) or planning to start some other psychological

intervention or psychiatric medication. 4. Any suicidal ideation (as measured by PHQ-9 Q9)

Date of first enrolment 14/03/2025

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Date of final enrolment 31/12/2025
Locations
Countries of recruitment Australia
Canada
China
Denmark
Egypt
England
France
Germany
India
Iran
Italy
Lebanon
Pakistan
Singapore
Spain
Sweden
United Kingdom
United States of America

Study participating centre

Imperial College London

Department of Computing South Kensington Campus Imperial College London London United Kingdom SW7 2AZ

Sponsor information

Organisation

Imperial College London

Sponsor details

Exhibition Road London England United Kingdom SW7 2AZ +44 (0)2075949456 rgitcoordinator@ic.ac.uk

Sponsor type

University/education

Website

https://www.imperial.ac.uk

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Charity

Funder Name

Empowered Human Foundation

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal

Intention to publish date

30/12/2026

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary

Available on request, Published as a supplement to the results publication