

Participant Information Sheet

Evaluation of Self-Initiated Humour Protocol

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Advisor: Dr Kamran Saedi (retired Psychiatrist)

You are being invited to take part in a research study of the Algorithmic Human Development group at Imperial College London. Before you decide whether you would like to take part, it is important to understand why the research is being done and what it involves. This information sheet tells you the purpose of the research study and aims to give you more detailed information about how the research study will be carried out. Do not hesitate to ask us if anything is not clear or if you would like more information. Take time to decide if you wish to take part. Thank you for reading this.

1) What is the purpose of the study?

We have developed the set of rule-based Self-Initiated Humour Protocol (SIHP)---that is 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 our pilot 8-week SIHP study in 2023, the participants, including those with mild to moderate symptoms of depression or anxiety, felt an improvement to their well-being, as well as an

increase in their use of self-enhancing laughter, 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 them for twenty minutes each day. With the study aiming to start in spring 2025.

2) Why have I been invited?

You have been invited either because you have responded to our invite online and in social media such as Facebook and Instagram. All adults with mild or moderate symptoms of depression or anxiety, based anywhere in the world, aged 18 or above who speak fluent English, have no 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 practicing 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 for at least three months can continue.)

3) Do I have to take part?

It is up to you whether you decide to join the research study. If you express interest in participating, you will first be given a consent form alongside this document. You will then be asked to complete our screening questionnaires to assess your eligibility to participate in the study, as our target demographic is a specific portion of the population. If you decide to take part you are free to withdraw at any time, without giving a reason by emailing ahd@ic.ac.uk. Your personal data will then be deleted. Your research data will be deleted if you withdraw prior to the completion of the study.

4) What will happen to me if I take part?

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 (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 (see part 3).

5) What do I have to do?

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 program start 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, optional weekly Q&A group Zoom sessions will be held to answer any questions you may have. 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 two weeks you daily practise the core of self-attachment technique by creating a compassionate and an affectional bonding with your childhood self. For this you would be interacting with childhood avatar, using a virtual environment, which will be created from your childhood photos of your choosing. Then in the subsequent six 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 three-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.

6) What are the possible disadvantages and risks of taking part?

The main issue is that taking part in the study will demand 20 minutes of your time in total every day for eight 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 practicing the protocol a little difficult since it may take you up some time to get used to them. 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 as detailed in the BMJ (<https://bmjopen.bmj.com/content/bmjopen/13/8/e073039/DC8/embed/inline-supplementary-material-8.pdf>). Two clinicians, who are members of the investigation team, will be available in such instances to provide additional support and guidance if necessary.

7) What are the potential benefits of taking part?

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.

8) What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way

you have been treated during this study then you should immediately inform the Investigator Prof Edalat (email: a.edalat@imperial.ac.uk). If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team rgitcoordinator@imperial.ac.uk.

9) What will happen to the results of the research study?

The results of the research study will be published as a paper in a relevant academic journal/conference. You will not be identified in this paper and we will share the paper with you for your information

10) Who is organising and funding the research?

Imperial College London is the study sponsor. This research is organised by the Algorithmic Human Development research group at Imperial College London. It is supported by the voluntary work of the non-profit Empowered Human Foundation (www.empowered-human.org).

11) Who has reviewed the study?

This study was given favourable opinion by Imperial College Research Ethics Committee (ICREC) and approval by Prof Alessandra Russo, Head of Department, Department of Computing.

Contact for Further Information

Prof. Abbas Edalat at: a.edalat@imperial.ac.uk or
Dr Neophytos Polydorou: neophytos@invincimind.com
Ruoyu Hu: ruoyu.hu18@imperial.ac.uk
Xinyan Ye: xinyan.ye19@imperial.ac.uk

Thank you for reading this.

You may retain this information sheet for reference and you can print a copy of your online consent via Qualtrics

Transparency Notice

How will your information be used about you?

Research Study Title: Self-Initiated Humour Protocol: A pilot study in the sub-clinical population

Imperial College London is the sponsor for this study and will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it appropriately. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

The study is expected to finish in **12/ 2025**.

For more information / confirmation regarding the end date please contact the study team, see **'WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED'** for contact information.

We will need to use information (including personal data and data created as part of the study) from **you** for this research project. This information will include your:

- Name
- Sex
- Contact details
- Date of birth
- Country of Residence
- Level of education
- Marital status
- Childhood photograph for use in generating a child avatar

People within the College and study team (see section 'Sharing your information with others') will use this information to do the research or to check your records (see information to be collected) to make sure that the research is being done properly and the information held (such as contact details) is accurate.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a unique study number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

LEGAL BASIS

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows:

Imperial College London - “performance of a task carried out in the public interest”; Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#)

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), (both organisations / Imperial College London) rely/relies on “scientific or historical research purposes or statistical purposes.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

SHARING YOUR INFORMATION WITH OTHERS

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

- Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service

providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

POTENTIAL USE OF STUDY DATA FOR FUTURE RESEARCH

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the [UK Policy Framework for Health and Social Care Research](#).

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

COMMERCIALISATION

Data from the study may also be provided to organisations not named in this participant information sheet, e.g. commercial organisations or non-commercial organisations for the purposes of undertaking the current study, future research studies or commercial purposes such as development by a company of a new test, product or treatment. We will ensure your name and any identifying details will NOT be given to these third parties, instead you will be identified by a unique study number with any sample analysis having the potential to generate 'personal data'.

Aggregated (combined) or anonymised data sets (all identifying information is removed) may also be created using your data (in a way which does not identify you individually) and be used for such research or commercial purposes where the purposes align to relevant legislation (including the GDPR) and wider aims of the study. Your data will not be shared with a commercial organisation for marketing purposes.

WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

- We need to manage your records in specific ways for the research to be reliable. This means that we may not be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Which will be stored digitally on

Imperial College London servers accessible only to necessary members of the investigation team.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information:

- by asking one of the research team
- by sending an email to ahd@imperial.ac.uk, or
- by ringing us on 02075988245.
- Our study information page at <https://humandevelopment.doc.ic.ac.uk/SIHP25/>

COMPLAINT

If you wish to raise a complaint about how we have handled your personal data, please contact the research team first by sending an email to ahd@imperial.ac.uk

Following our response, if you are not satisfied please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO)- via www.ico.org.uk. Please note the ICO does recommend that you seek to resolve matters with the data controller (us) first before involving them.