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PARTICIPANT INFORMATION SHEET

Study title: A randomised controlled trial of a brief cognitive task intervention to support NHS staff experiencing intrusive memories of traumatic events from working in the COVID-19 pandemic (GAINS-2)

Study Number: P1V-GAINS-IN02

Invitation to take part in the study

You are being invited to take part in a clinical research study. Please take a few minutes to read what it is about before you decide whether or not to participate. The study is sponsored by P1vital Products Ltd - we are both the sponsor and research site for this study.

What is the purpose of the study?

As an NHS staff member who has worked in some capacity with COVID-19 patients during the pandemic, you may have been exposed to significant, stressful, or psychologically traumatic events. Whilst these events can be common at work, the increased number compared to usual is a challenge. Many staff have subsequently described intrusive unwanted memories of these events with images that pop into their mind's eye suddenly, such as seeing a patient's face or an item of equipment. These intrusive memories can be fleeting but distracting so that they affect one's concentration and the ability to do everyday tasks. They can even be quite distressing.

A brief online intervention which includes a 25-minute cognitive task, has previously been found to reduce the number of intrusive memories for people who have had traumatic events. Our study compares the effect of an auditory task, a visual task and treatment as usual on the number and the impact of such intrusive memories for NHS staff who have worked during the pandemic. The online intervention takes about 40 minutes in a first session guided by a researcher (by video call), and after that can be done independently in your own time (about 25 minutes each time). There is no need to meet in person.

Who can take part?

To take part you will have experienced at least one traumatic event related to your clinical work in the NHS during the COVID-19 pandemic and be currently experiencing intrusive memories of the event(s) (at least 3 per week). You will be 18 years or over and be able to read, write and speak English.

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Do I have to take part?

No – it is entirely up to you. If you do decide to take part and give consent (see point 2 below), please keep this information sheet (e.g., save it on your phone/computer). You can still withdraw at any time if you change your mind, and without giving a reason. Whether or not you decide to take part will not affect your employment or future medical care.

What will happen to me if I take part?

You can complete the entire study remotely on a computer, smartphone or tablet. The whole study will last about 6 months. There will be one or more virtual visits with a researcher (e.g., via video call using Microsoft Teams) but no in-person meetings. You will be asked to complete online questionnaires on four occasions.

We have broken down the study so that you can understand what it involves and exactly how long it will take:

1. Fill in a questionnaire to check your eligibility (5 minutes online)

- After you have read this information sheet on the study website, you will be asked to complete a brief online questionnaire anonymously to indicate if you might be eligible to take part in the study. We will ask for your consent to fill in this questionnaire using a checkbox.
- If you are eligible to take part in the study, you will be asked to provide your name, telephone number and email address. You can choose to book a meeting with a study researcher online, or wait for a researcher to contact you to arrange a suitable time.

2. Meet with a researcher to take your consent (30 minutes video or phone call)

- You will have the opportunity to discuss the Participant Information Sheet and ask any questions you may have to be sure that you understand the content and procedures.
- If you agree to take part, you and the study researcher will sign the consent form located at the end of this document using a simple electronic signature via email. The study researcher will send you an electronic copy of the consent form to keep.
- If you consent, the researcher will ask you some questions to check your eligibility, your contact details and your job role.
- If you are not eligible to take part in the study, we will let you know where you might find support or advice if you need it.

3. Complete a daily questionnaire to confirm if you are eligible (1 minute per day for 1 week, online)

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- Over seven days, we will send you a reminder each day by email with a link to fill in a brief online questionnaire of how many intrusive memories you have had that day.
- After the seven days, we will let you know if you are eligible to continue with the study. If you are not eligible to continue, we will delete your contact details and send you details of where you might find appropriate support or advice if you need it.

4. Complete a set of questionnaires (20 minutes online)

- We will send you a link to fill in some online questionnaires. These questionnaires ask about your demographic details and health, your experience of the stressful or traumatic event(s) you encountered at work, difficulties you may be experiencing, and how you feel about your work.

- You will then be randomly allocated to do one of three things:
    A. An auditory online cognitive task (which includes listening to music) – 40% chance.
    B. A visual online cognitive task (which includes playing a computer game) – 40% chance.
    C. Treatment as usual (the routine care you would otherwise access) – 20% chance.

- The study researcher will contact you to inform you of the next steps.
    If you are assigned to A or B, you will follow Step 4A and 4B.
    If you are assigned to C, you will follow Step 4C.

4A. Meet with a researcher to use the online intervention for the first time (1hour, video call)

- If you are allocated to one of the two cognitive task interventions, you will be contacted by a study researcher to arrange a suitable time to go through the intervention for the first time. You will be asked to:
    1. Log in to the online intervention
    2. Complete either an auditory task (which includes instructions and listening to music for 20 minutes) or a visual task (which includes instructions and playing a computer game for 20 minutes)
- You might be asked to briefly list your intrusive memories and bring one to mind before doing the task.
- The session will be audio recorded for training and assessment purposes.

4B. Access the online intervention in your own time (approx. 25 minutes each time as often as you like for 4 weeks)

- After the first time, you can do the intervention as many times as you like during the next 4 weeks. You can do it on your own or with help from a researcher. Some people only need to use it a few

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times.During this time, we will send you reminders by text or email (as you prefer) to help you use the intervention.

- At the end of the last week of accessing the intervention we will email you a link to complete a brief feedback questionnaire, which asks about your experience of using the intervention.
- You will continue to have access to the intervention for the remainder of the study (up to 24 weeks) if you wish.

4C. Receive treatment as usual

- If you are allocated to receive treatment as usual, you can continue to receive any routine care that you would otherwise access, but you will not need to give us more of your time in the following 3 weeks.

5. All participants: Complete a daily questionnaire three more times in weeks 4, 12 and 24 (1 minute per day for 1 week each time, online)

- Over each of these seven-day periods, we will send you a reminder each day by email with a link to fill in a brief online questionnaire of how many intrusive memories you have had that day.

6. All participants: Complete a set of questionnaires three more times at 4, 12 and 24 weeks (15 minutes each time, online)

- We will email you a link to fill in some online questionnaires again, which are similar to the first set of questionnaires.

7. Complete optional feedback interviews (30 minutes phone/video call)

- If you accessed an online intervention, you may have the option of meeting a researcher from Nottingham University to complete a feedback interview at 4 weeks and/or 12-24 weeks. The researcher will ask you a number of questions about your experience of using the intervention including suggestions for improvement and potential barriers and challenges that you may have encountered. The interview will be audio recorded.

8. If you were not allocated to receive the intervention, you will be offered the option to access the intervention for a period of 6 months after the trial's end date.

Expenses and payments

If you decide to take part in the study, you will be offered a £15 voucher after completing the week 4 questionnaires, and a £15 voucher after completing the last set of online questionnaires or feedback interview in appreciation of your help with the study.

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What will I have to do?

As a participant in this study, we ask that you:

- Be willing and able to complete the study procedures.
- Be willing and able to be contacted by the research team during the study period.
- Have internet access.

Which parts of the study are different to the clinical care I would normally receive?

The online intervention and the questionnaires you complete are not normally part of clinical care.

What are the possible side effects, disadvantages and risks of taking part?

There are no major risks associated with taking part in the study. Some people may find briefly listing and bringing to mind their intrusive memories distressing. However, this is very brief, and we will not ask you to think about or talk about the traumatic events in any detail.

This procedure has been tested in several previous studies with no adverse consequences. A researcher will go through the intervention with you the first time you use it and will be available to help with the intervention for the first 4 weeks.

Most people find the intervention approach easy and not very distressing. If we learn important new information about possible risks or other information that might affect your willingness or ability to continue in the study, then we will tell you about it. If you take part in this study, we will ask you to report any untoward medical occurrences by questionnaire.

What are the possible benefits of taking part?

By taking part in this study, you may have fewer intrusive memories of stressful/traumatic events you have encountered at work. Our previous research has shown that a version of the intervention can reduce intrusive memories after different types of traumatic events. We are conducting this study to compare the effect of an auditory task, a visual task and treatment as usual on the number of intrusive memories for NHS staff who have experienced traumatic events in their line of work during the COVID-19 pandemic.

What if relevant new information becomes available?

We will tell you if any new information becomes available which may affect your decision to continue in the study. We will give you an updated information sheet and discuss this with you. If you decide to continue in the study, you will be asked to electronically consent to an updated consent form.

What will happen if I don't want to carry on with the study?

You can leave the study at any time. Your participation in this research study is voluntary (your choice). If you decide to withdraw from the study, please tell us immediately using the contact details listed on the

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last page of this information sheet. If you do withdraw after taking informed consent, we will use any anonymous data collected up to the time of your withdrawal.

Withdrawal from the study

It is possible that the researchers may decide to withdraw you from the study if the principal investigator considers it necessary. If this occurs, we will explain the reasons to you. Possible reasons are:

- Ineligibility (either arising during the study or retrospectively having been overlooked at screening)
- An adverse event that results you no longer being able to comply with study procedures.
- Significant protocol deviation.
- Withdrawal of consent.

What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you want to complain about how researchers have handled your information or if you need further information, you can contact the study team on +44(0)1865 522508 or gains@p1vital.com, and we will do our best to answer your questions. If you are not happy after that, you can contact the Data Protection Officer on dpo@p1vital.com. If you remain unhappy with our response or believe we are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

Harm

Any participation in a clinical study involves a risk, however small it is. Even if there is no fault, the sponsor accepts responsibility for damage caused to the participant (or in the event of death, his/her dependants), directly or indirectly linked to his/her participation in the study. The sponsor has taken out insurance for this responsibility.

Will my taking part in this study be kept confidential?

Yes, your taking part in the study will be kept confidential. If you have high levels of distress (e.g., thoughts about suicide or harm to others) during the study, we may encourage you to discuss this with your General Practitioner (GP).

We are not obliged to inform your employer or manager of any of these details. If at any point during the study you reveal information that suggests professional malpractice, we will encourage you to report this to your Hospital's Freedom To Speak Up (FTSU) Guardian and/or to follow your Trust Whistleblowing Policy.

The information you provide during the study is the research data. Any research data from which you can be identified (e.g., name, contact details, audio-recording) is known as personal data. Individuals from the sponsor research team and their authorised delegates will use this information to do the research

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or to check your records to make sure that the research is being done properly. Those members 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 identification code number instead. Personal data including your contact details will be stored separately from other research data in password-protected files, devices and online platforms and will be kept for a maximum of 6 months after the end of the study (with the exception of consent records which will be retained for 5 years after final publication / public release), after which time it will be destroyed (files will be deleted). Audio-recordings will be stored under your identification code in password-protected files and will be destroyed once they have been transcribed (i.e., written out). Transcriptions will be externally transcribed, and once transcribed, transcripts of audio-recordings will be edited to remove identifying information and stored with other research data. All data will be kept either in locked filing cabinets or on sponsor password-protected network. We are obliged to keep research data (including consent records and questionnaire/intervention data) for a period of at least 5 years after final publication/public release, and de-identified data may be archived in an online repository. We will keep all information about you safe and secure.

If you take part in this study, you will be asked to set up a user account (with a username and password) to complete the study intervention and questionnaires online. During the study, questionnaire and intervention task data will be collected from you and stored electronically on the P1vital® ePRO and i-spero® systems. P1vital Products Ltd is fully compliant with the General Data Protection Regulation and Data Protection Act 2018 and have appropriate data security policies and procedures in place. Data (including personal identifiable data) will be stored securely on these servers which are hosted in the European Union and archived at the end of the study.

If you decide to stop taking part in the study part way through, we will not collect any further information from you, but will keep any information we have already collected and use it in this research. We may choose to directly quote something you have said word for word in a publication arising from this study, or in our recruitment materials. If we do this, we will first make sure that any identifying information is removed or disguised.

We may also share data with Uppsala University in Sweden and University of Nottingham (if you agree to take part in an optional feedback interview) in the United Kingdom (UK) or other interested researchers but only through a pseudonymised (i.e., de-identified) database after removing all information that identifies individuals. Where data are being shared with a third party, there will be an appropriate data sharing agreement between organisations to ensure your information is safe. By signing this form, you understand that the study team will be collecting and using personal data about you for the study. You have the right to access and receive a copy of your personal data, and other supplementary information upon request. You are entitled to ask the study researcher what data are being collected about you and their use in connection with the study.

What will happen to the results of the research study?

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The results of the research will may be written up for publication in scientific journals and may be presented at scientific conferences and public events. We will write our reports in a way that no-one will be able to identify you. At the end of the study, we will send you details of where you can access the published results once they become available.

Any anonymised data collected from your intervention use after you have completed the trial will only be used to optimise the intervention and will not be considered research data. **Participating in future research**

If you agree to be contacted regarding future research, we will hold your contact details in a password-protected database until they are no longer required. Your contact details will be kept separate from the study data and will be held on a password-protected sponsor computer/network. Contact about future research will come from our research team in the first instance. Agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time you wish.

Who is organising and funding the research?

P1vital Products Ltd., Manor House, Howbery Park, Wallingford, Oxfordshire, OX10 8BA, UK, is funding this research and is called the 'Sponsor'. P1vital Products Ltd. is supported by additional funding from Wellcome Trust discretionary project grant award (223016/Z/21/Z) in mental health. P1vital Products Ltd is the controller of the data. Administrative and organisational support for the study will be provided by P1vital Products Ltd., a company specialising in digital mental health solutions for the pharmaceutical and healthcare sectors.

Who has approved the study?

The study has been reviewed and approved by the Wales Research Ethics Committee 4

It is the task of the Ethics Committees to protect people who take part in a clinical trial. They make sure that your rights as a patient and as a participant in a clinical study are respected, that based on current knowledge, the balance between risks and benefits remains favourable to the participants, that the study is scientifically relevant and ethical. You should not under any circumstances take the favourable opinion of the Ethics Committee as an incentive to take part in this study.

Further information and contact details

If you would like general information about research, this can be found on many websites including www.crncc.nihr.ac.uk/ppi/ppi involve.

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

- At www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to **gains@p1vital.com**, or
- by ringing us on **+44(0)1865 522508**

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If you would like more information about this study and whether you should participate, please contact one of our study team on the number given below. You could also ask family, friends and your GP about whether to take part. Throughout the study you can contact us to answer questions.

You will be given a copy of this information sheet and a signed consent form to keep.

Contact details for Dr Amy Beckenstrom and her study team:

Email: gains@p1vital.com

Tel: +44(0)1865 522508

Thank you for taking the time to read this.

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CONSENT FORM

Study title: A randomised controlled trial of a brief cognitive task intervention to support NHS staff experiencing intrusive memories of traumatic events from working in the COVID-19 pandemic (GAINS-2)

Study Number: P1V-GAINS-IN02

Participant Identification Number: .....

PLEASE INITIAL BOX

I confirm that I have read and understand the information sheet dated 13th June 2023 (final version 3.0) for the above study. I have had the opportunity to consider the information, ask questions and had these answered satisfactorily. ☐

I understand that the study involves: ☐

a) keeping a record of how many intrusive memories I have each day for one week initially, and again 4, 12 and 24 weeks later ☐

b) either having access to an online intervention (which involves listening to music or playing a computer game) for 24 weeks or treatment as usual for 24 weeks ☐

c) possibly briefly listing my intrusive memories and bringing them to mind as part of the intervention (without going into any detail) ☐

d) meeting with a researcher by phone/video call at least twice, and possibly an optional meeting to give feedback about the intervention. ☐

I understand that guided intervention sessions will be audio recorded by researchers for training and assessment purposes. ☐

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. If I withdraw from the study, I agree that data collected up to the point of withdrawal will be retained. ☐

I understand that data collected during the study may be looked at by individuals from the Sponsor research team and their authorised delegates, where it is relevant to me taking part in this research, I give permission for these individuals to have access to my data. ☐

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I understand that my personal data, will be used and stored as described in this information sheet.	☐
I am aware that the results may be made available to other researchers but only in a pseudonymised database after removing all information that identifies individuals.	☐
I understand that data will be collected and stored electronically in the P1vital® ePRO and i-spero® systems.	☐
I agree to the use of anonymised direct quotes in research reports, publications and recruitment materials.	☐
I agree to be contacted to take part in an optional feedback interview about my experience of using the intervention	☐
I agree to be contacted about other ethically approved research studies for which I may be suitable and I understand that agreeing to be contacted does not oblige me to participate in any further studies.	☐
I agree to take part in the study.	☐

Signature: Date: Time:

Full name of Participant:

Signature: Date: Time:

Full name of investigator taking consent:

When completed: 1 copy of this form for participant; 1 copy of this form for researcher Investigator Site File