Participant Information Sheet
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Treating Depression with Self-Compassion using Virtual Reality: Feasibility and Acceptability Study (VRCom-F)

We would like to invite you to take part in a research study

- We are inviting you because you registered with Camden & Islington Psychological Therapies Service (**iCope**) for help with depression and you gave your consent to be contacted about research studies you might like to take part in.
- Learning and practicing self-compassion can help us challenge negative and self-critical thoughts and can help people living with depression feel better
- We want to find out if a new therapy that combines self-compassion with virtual reality technology is helpful for people with depression
- This study would take place while you are on the waiting list with iCope for treatment for depression (NHS Camden & Islington Psychological Therapies Services) and so before you start any NHS therapy sessions
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect your current or future care from the NHS.

Important things that you need to know

- Taking part in the study does not replace or alter the therapy you will be offered by the NHS so if you decide to take part you will need to attend extra appointments at UCL.
- Please take time to read the following information carefully. Discuss it with friend and relatives if you wish.
- Please ask us if anything is not clear of if you would like more information.
- We will give you £40 of retail vouchers as a thank you for your time and cover your travel expenses.
- You can stop taking part in the study at any time.
- We will keep the information you share with us safe and secure and follow all privacy rules

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How to contact us

If you have any questions about this study, please talk to the researchers who organise it: Dr Kilford or Prof. King

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j.king@ucl.ac.uk
020 7679 5993

UCL Research Department of Clinical, Educational and Health Psychology, 1-19 Torrington Place, London WC1E 7HB

1 Why am I being invited to take part?

You have been invited because you are on the waiting list with Camden and Islington Psychological Therapies Services (**iCope** www.icope.nhs.uk/camden-islington) for therapy for depression are aged 18 years or older and when you registered with the service you gave your consent to be contacted about research studies you might be interested in taking part in. We hope that 50 people who are registered with iCope for help with depression will take part in this study in total.

2 Why are we doing this study?

Our research team has been working for several years to develop a virtual reality (VR) based therapy for depression. Research shows that compassion plays an important role in our lives and can influence our general well-being and mental health. Our research has shown that VR technology can be used to help people with depression be more **compassionate** towards themselves.

We offered people the chance to wear a VR headset and experience what it's like to be in a 'virtual body', known as an avatar. They would reassure a character who appeared upset, and then have their own reassuring words played back to them. We found that this helped people to think about themselves more positively and even reduced symptoms of depression.

Since we did this earlier research, we have been working to improve this original VR therapy to make sure that it makes the most of recent advances in VR technology, and to make it more flexible and realistic. We have also organised discussion groups so that people who have experienced depression could share their opinions and advice as to how to make the VR therapy the most helpful for as many people as possible.

Now that we have updated the therapy, we are looking to see if people who are currently on the waiting list for psychological therapy within the NHS would find it helpful and practical to take part in this new VR therapy. To do this, we are running a type of clinical trial called a feasibility and acceptability study (you can read more about how clinical trials work here: www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx).

We hope this research will help us find out what people think about the therapy now that we've updated it, and how taking part in it compares to being on the waitlist and not taking part in the VR therapy. We plan to use what we learn in this study to further improve the VR therapy and carry out more research to get it ready to be used in the NHS more widely if the results suggest it is helpful for people.

3 Do I have to take part?

No. It is entirely up to you to decide whether you would like to take part in this study. We will go through this information sheet with you, and you will be able to ask any questions you have about it. If you do decide to take part, you will be given this information sheet to keep and you will be asked by one of the researchers to sign a consent form. If you decide to take part, you will be free to change your mind and withdraw from (leave) the study at any time without having to give a

reason as to why you want to do so. Importantly, a decision to withdraw at any time or a decision not to take part will not affect the standard of care you receive or your future medical care or legal rights.

4 What will happen if I take part?

If you decide you think you would like to take part, a member of the research team will get in touch to arrange an appointment with you. This appointment will last around 1.5 hours and you will be able to take rest breaks.

In this appointment we will discuss the study with you and ask you some questions to make sure it is safe and practical for you to take part in the study and answer any questions you might still have about whether taking part is the right decision for you. You can also contact a study researcher before this appointment if you have any other questions or would like more information.

This appointment (and all other appointments for the study) will be at the UCL University Clinic, part of the Camden and Islington Psychological Therapies Service located at UCL (1-19 Torrington Place, WC1E 7HB; nearest Tube station: Goodge Street). We will do our best to schedule your appointments at convenient times for you.

If you decide you would like to take part in the study, you will be asked to sign a consent form and then we will ask you to complete some questionnaires. These questionnaires will include questions about yourself (such as your age, gender and ethnicity), your symptoms of depression and anxiety, and any medication you are currently taking for these symptoms, and how your depression is affecting your day-to-day life and well-being. There will also be some questionnaires about your experiences of giving and receiving compassion, how you respond to yourself in different situations, and how you experience different kinds of positive emotions.

After this, the researcher will use a website to place you at random to one of two groups:

1. Control Group
2. Virtual Reality Group

The reason that there are two groups is because this type of clinical trial needs to have a control group. This a group of people who take part in all parts of the research except for the VR therapy so that we can compare the groups to see what effects the VR therapy had on those who tried it versus those who didn't. For this to work, it's important that people are placed in a group at random and so there will be a 50/50 chance of you being placed in either group - the researcher will tell you which group you have been placed in during your appointment.

We won't be able to place you into a group before you decide whether you would like to take part in the study, so it's important that you take both scenarios into account when thinking about whether taking part in this study is right for you. Whichever group you are placed in you will stay on the waiting list for psychological therapy with the iCope service while you are taking part in this study and will still be invited to attend this after the study is finished.

If you are in the **Control Group**, you will be asked to come back for two follow-up appointments. This is so we can see how taking part in the VR therapy compares to being on the waitlist with iCope, and to learn about your experiences of being part of a study like this. The first follow-up

appointment would be held around 2 weeks later, lasting around 30 minutes. The second (final) follow-up appointment would be held 4 weeks after that (i.e., 6 weeks after your first appointment) and last for around 1.5 hours.

If you are in the **Virtual Reality Group**, you will be invited to come for four, one-to-one, 1-hour Virtual Reality sessions held over a period of approximately 2 weeks at the UCL University Clinic. You will also be invited to take part in some home practice activities between sessions, such as keeping a private diary of your reflections on the session activities if you would find this helpful. We will provide you with the materials you need to do this, including lending you a tablet with the activities loaded on it. You can find out more about the **Virtual Reality Therapy** here: www.virtualcompassion.net/virtual-reality-therapy

In the 4th session, we will also ask you to complete some follow-up questionnaires. We will also ask you to come back for a final follow-up appointment 4 weeks after your last virtual reality session (approximately 6 weeks after your first appointment) which will last for around 1.5 hours.

Whichever group you are in, in these follow-up appointments we will ask you to complete some more questionnaires, including some of the questionnaires we asked you at your first appointment. In your final appointment, we would also like to ask you some questions about your experience of taking part in the study and answer any outstanding questions you might have about it. There may also be opportunities for you to be involved in further research asking for your feedback about your experiences of taking part in the study in more detail. If you would be happy to be contacted with more information about this, there is a section on the consent form where you can tell us that we can contact you to invite you.

5 Things to consider before deciding whether to take part

Am I able to take part?

To be eligible to take part, you need to meet the following criteria:

- Vaccinated against coronavirus
- Not clinically extremely vulnerable (at high risk of serious illness from coronavirus)
- No history of seizures, brain injury or Epilepsy, head or neck injury or musculoskeletal problems
- Confident speaking, listening to and reading English
- Able to attend the study appointments

The first two criteria are to make sure that risk of COVID-19 risk, and transmission is minimised for all our participants and researchers. The third is because these health conditions can make it unsafe to use virtual reality equipment.

It's also important that you are confident in speaking, reading and listening to English as the study questionnaires and VR therapy are currently only available in English. If you usually use spectacles and/or a hearing aids you can still use these with the VR headset, as long as they can fit within it.

While you're taking part in the study, we do ask that you don't take start any other types of psychological therapy or take part in other research studies about depression or mental health.

This is because it can be confusing to try out different therapies at the same time, and because the appointments for this study are already potentially quite time-consuming. However, please do continue to take any regular medication, including any medications you have been prescribed for depression and anxiety.

Finally, we ask that you think about whether you would be able to attend the full number of suggested appointments for whichever group you are put in. We will do our best to schedule your appointments at times that work for you, but it's important we try to fit all of your study visits in within the 6-week window so that you don't have to wait longer than this for your appointments with iCope to begin.

If you have any concerns or questions about whether you'd be able to take part, or you're not sure whether you would be eligible to do so, please do not hesitate to contact a member of the research team so we can discuss this together.

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

If you don't want to carry on with the study, you will be free to withdraw from it at any time, without having to give a reason. Withdrawing from the trial will not affect the standard of care you receive or your future medical care or legal rights. We will let iCope know that you are no longer taking part in the study so that they know you're ready to continue with your clinical care.

If you choose to leave the study, you will be asked what you wish to happen to any information you have already shared with us (see also **What will happen to my data?**).

What are the possible disadvantages or risks of taking part?

Before you decide whether to take part it's important to consider the possible risks and inconveniences to carefully weigh up whether taking part is the right decision for you. These are outlined below:

COVID-19 Infection. All researchers will always follow UCL and NHS COVID-19 protocols to minimise the risk of COVID-19 transmission or infection. These include minimising contact between people, disinfecting surfaces and equipment, washing/sanitising hands at the start and end of visits, maximising ventilation during visits and regular testing and vaccination of researchers and participants. For further details about how we will minimise COVID risks specific to the VR equipment please see **Virtual Reality Therapy:** www.virtualcompassion.net/virtual-reality-therapy

Time Commitment If you decide to take part, it will require some of your time. The time commitment will be greater if you are placed in the **Virtual Reality Group**, particularly during the first 2-3 weeks of the study, in which there will be multiple appointments in a short space of time. You will also be invited to take part in some home practice activities between sessions if you would find this helpful.

Emotional and Psychological Wellbeing A big part of this research study involves questionnaires. Some of these we will ask you to fill out yourself, and some of these a researcher will go through the questions with you. These questionnaires have been used before in other research with people with depression before, but they do cover some topics which could bring up difficult memories or feelings, such as questions about your anxiety and depression, how your symptoms

are impacting your life, and questions about your emotional experiences and how you relate to yourself during these times. If you would like to know more about the content of these questionnaires, please do get in touch with a member of the research team for more details.

If you were to feel uncomfortable or upset by any of the questionnaires in the study you will always be able to take a break, choose to complete them at another time or choose not to complete them. You will be able to leave the study at any point you wish to and if you decide to take part, we will give you a contact sheet with details of who to contact, and how and when you can contact them.

VR Equipment We will be using widely available VR equipment and following the equipment manual and health and safety information. You will never need to use the VR equipment by yourself, and there will always be a researcher who is trained in how to set up the equipment safely to minimize risks of using VR equipment. The equipment will only ever be used in a safe environment while you're sat down, to minimise the risk of accidental injury. For your safety, it's important that you are not under the influence of alcohol or drugs or experiencing anything else that might affect your motion and balance, when using the VR equipment.

The equipment we are using is some of the latest technology in VR and is calibrated in such a way to reduce risks of nausea and/or disorientation. However, we can't completely rule out these risks. If you think you are at particular risk of this occurring (such as being highly susceptible to motion sickness or experiencing nausea due to pregnancy or a medical condition) please do get in touch with us to discuss this in more detail to help you decide if taking part is right for you or not. If you do experience any side effects, you can stop or take a break at any time.

It is also possible that after using the VR equipment you may experience some short-term effects on your vision for up to approximately 30 minutes after us. This risk is small, and there is no evidence of long-term effects, but you may need to be cautious about the activities you plan to do immediately after using the VR in case this happens. For example, we would not recommend you drive in the 30 minutes after a VR session.

VR Therapy The VR therapy in this study is still under development. This means that there isn't the same amount of existing research for this therapy as there is for the therapies that are currently available from the NHS for depression. This is why we are doing this study, and why everyone in the study will still be offered standard therapy from iCope after the study. It also means we are running the therapy in quite a short period of time, because we don't want to slow you down in starting therapy with iCope. However, this means your VR therapy appointments will take place over quite a short period of time (approximately 2 weeks), which could be quite intense. If you feel fatigued or anxious about any of the sessions or the activities in them, you will be able to take a break, ask to complete any or all of these activities at another time or decline to complete any or all of these activities at any time.

Even for existing treatments for depression, it is unfortunately never easy to predict what the outcome will be for someone. However, treatments that are currently offered in the NHS have been extensively studied so that it is possible to give an estimate of roughly how many people with depression will find it helpful. We are still doing the research, so we can't guarantee that the sessions will help you, and we can't rule out the possibility that the therapy might make you feel worse.

What we can say is that in our previous research with a small group of roughly 15 people waiting for treatment for depression in IAPT services, everyone found it to be helpful, enjoyable and interesting and their symptoms of depression were lower afterwards than before. Since that study, we have run 4 discussion groups with people so that people who have experienced depression could share their opinions and advice as to how to make the VR therapy the most helpful for as many people as possible.

To help you decide whether taking part in this study is right for you, you can read about what you can expect to see and hear in VR, and the other activities that make up the therapy here: www.virtualcompassion.net/virtual-reality-therapy The VR therapy does involve interacting with a virtual person who is upset, which some people may find uncomfortable or distressing. However, there are different options you can try out in the different sessions (such as changing the identity of the virtual people), and you will be able to work with your researcher to decide which options would be the best fit for you as you go.

As with all parts of this study, you will be able to stop taking part at any time you choose, and without giving a reason. There will also be support available to you throughout the study - we will give you a contact sheet with details of who to contact, and how and when you can contact them, in case you experience any negative effects relating to any aspect of this study.

What are the possible benefits of taking part?

You may benefit from taking part in this study because you may receive a new type of therapy that has previously been shown to have a positive impact on people's wellbeing, and in particular, to help people with depression be more compassionate towards themselves, think about themselves less critically and reduce their symptoms of depression.

Although we are hopeful that you will see the same benefits as observed in other people, this may not be the case, which is why we are doing this research study. While we cannot promise there will be a direct benefit to you personally, we hope that this research will help us to develop a VR therapy for depression that is as helpful as possible for as many people as possible. Taking part will therefore be a real opportunity to meaningfully influence what this new VR therapy is like.

6 Further information about the research study

Will I be reimbursed for taking part?

As a thank you for your time, you will receive a £10 and then a £30 voucher (lovetoshop.com; a leading UK multi-retailer gift voucher) at your first and last visit (or at any point that you decide to withdraw from the study). We will cover travel costs for your journeys to and from our clinic at UCL for your appointments. Please note that we can only pay you back for journeys on public transport within London Zones 1-5. If you need to use an alternative form of transport, please get in touch and we can talk with you about your needs and what adjustments are possible before you decide whether taking part is right for you.

What will happen at the end of the study?

When you have finished taking part in the study (either because you have completed the final

appointment session or because you have decided to leave the study or are unable to continue) we will let the iCope Care Team know so that can contact you about arranging your next appointment with them.

At the end of the study, we will analyse all of the information you have shared together with other people's information. We will use the results to inform the development of the VR therapy in our future research. If you consent for us to do so, when we have finished analysing the results of the study, we will send you a report summarising the study findings and explaining how your involvement has influenced the development of the therapy.

We also hope to publish the study results and/or present them at scientific conferences, which we hope will improve understanding of how using VR as part of psychological therapy could be used to help people with depression. You will not be able to be identified in any reports or publications.

Will my doctor be informed of my participation?

The study researchers work closely with the iCope service and hold research contracts with UCL, Camden and Islington NHS Trust or both organisations. If you decide to take part, we will put a copy of your consent form in your clinical records so that the iCope Care Team knows you are taking part in this study, and they should wait until after you have finished taking part to schedule your next appointment. We won't write to your GP to tell them that you have decided to take part.

Will my taking part in this study be kept confidential?

Yes. Only the study researchers will have access to any personally identifying information you share with us (e.g., your name and contact details). This information will be stored securely at the Department of Clinical, Educational and Health Psychology, at UCL and will be kept strictly confidential.

We will not pass on any information you share with us during the study to the iCope Care Team or your GP unless we become concerned for your safety or another person's safety (e.g., if you express an intention to harm yourself or another person, or that your depression is getting worse). This is so that you can be referred for more support and why we ask for your GP details. If this was the case, we would discuss this with you first. If confidentiality had to be breached for any other compelling and legitimate reason, we would inform you of any decisions that might limit your confidentiality.

The research team will take all reasonable steps to protect your privacy. 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 randomly generated code number instead. The section below explains more about how we will keep all the information you share with us safe and secure.

What will happen to my data?

We will need to use information from you in order to carry out this research study. UCL, based in the United Kingdom, is the sponsor for this research and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

We will only use the minimum personally identifiable information about you possible. This information will include your name and contact details. We will use this information to contact you

during the study, and if you give your consent, to send you a copy of the study report and/or invite you to take part in further research after the study is finished. We may also use this information, if necessary, to refer you for further clinical support, as described above.

Your **research data** is all the other information you share with us, such as your answers to questionnaires. We need to manage your **research data** in specific ways for the research to be reliable and accurate. This means that we won't be able to let you access or change the research data we hold about you. This information will be coded using a unique identification number that is randomly generated and doesn't include any identifiable information about you. This means that it will not be possible to identify you from any of your **research data**. This information will be stored separately from your contact details and other personal information that could reveal your identity.

You can stop being part of the study at any time, without giving a reason. If you do this, we will ask you what you would like us to do with any information you have already shared with us. We will keep a secure copy of the data code at UCL so that if you decide you want us to remove your data from the study, we could use these codes to look up your data to do so. After we have finished the study, we will fully anonymise the data. Please note that after this, it may be difficult or impossible for us to remove your anonymised data.

During the study we will not be collecting any research data from your iCope clinical records. However, if you are happy for us to do so, after you are finished with the study and start your routine appointments with iCope we would like to collect your answers to a questionnaire about your depression symptoms that the iCope service often ask people to fill out during their appointments as part of our follow-up research. We will only collect this information if you have given us your additional permission to do so on the consent form. If you would like to see a copy of this questionnaire before deciding, please ask one of the researchers.

All **research data** will be stored in a secure electronic database specifically created for the study, hosted by the University of Bangor. The database uses industry standard techniques to provide security and complies with the UK Data Protection Act 2018 and the EU General Data Protection Regulation (GDPR). The database will be managed by members of our team at the University of Bangor (https://nworth-ctu.bangor.ac.uk). Only named members of the research team will have access to the database, and no data will be transferred via email or be sent outside the UK.

If you are in the **Virtual Reality Group**, we will also need to take some recordings of your body movements and voice. If you would like to, you will also have the option to personalise some aspects of the VR experience, for which we would need to take a photograph of you. All of this information will only be used to run your own VR experience, and all the information you share with us to help us create this will be securely stored at UCL and will only be accessible to the named research team. These recordings will only be used to run your VR experience, during which they will be uploaded onto a device not connected to the internet. After the VR experience, this information will be wiped from the device. So that you can re-visit your VR experiences as part of the home practice activities, we will load your recordings onto a tablet that we will lend you to take home between the 4 Virtual Reality sessions. All recordings or images created during the VR sessions are not research data and so after you have finished taking part this information will be securely deleted and will not be analysed or shared beyond UCL. This includes the recordings on the tablet, which we ask you to return to us so that we can securely wipe the recordings from it.

For more information about how recordings are used in the VR experience please see: www.virtualcompassion.net/virtual-reality-therapy

We would also like to ask you some questions about your experiences of taking part. These questions can either be completed by talking to one of the researchers, or in writing. If you decide to answer these questions verbally, we will record the discussion using an digital voice recorder. The recordings will be stored on a secure, password protected computer, in a locked office in an access-controlled building until they can be typed up. The recordings will be typed up (a process called transcription) as soon as possible either by the study researchers or by a professional transcription service that has been approved by UCL. The transcription service will sign a confidentiality and data security agreement, meaning that they will only be allowed to process your data in the specific ways we have instructed them to and not use it in any other way. When the recordings are typed up, we will make sure any information that could identify you is removed, after which point the recordings will be securely destroyed.

Personally identifiable information will be stored securely at UCL for up to a year after the study has ended. Anonymised research data will be stored for up to 10 years after the study has ended. The fully anonymised research data may be archived online as "open data" following publication of any resulting papers.

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

- in this leaflet www.hra.nhs.uk/patientdataandresearch
- by contacting Dr Kilford (e.kilford@ucl.ac.uk, 020 7679 5774)
- at https://www.hra.nhs.uk/information-about-patients/
- in our general research participant privacy notice for health and care research at: https://www.ucl.ac.uk/legal-services/privacy/ucl-general-privacy-notice-participants-and-researchers-health-and-care-research-studies

Who is organising and funding the research?

This study is funded by the National Institute for Health Research (NIHR) Invention for Innovation (i4i) programme (ref: II-C8-0518-20002). NIHR is a UK Government agency which funds research into health care. The research is being led by John King who is a Professor of Clinical Cognitive Neuroscience at University College London and a Clinical Psychologist. The research is sponsored by University College London.

Funded & supported by NHS National Institute for Health Research

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect participants' interests, safety, rights, well-being and dignity. This study has been reviewed and been given a favourable opinion by [Insert: Research Ethics Committee name and reference number].

What if there is a problem?

Every care will be taken by the study team during this research, and we do not expect any harm to come to you because of taking part. If you decide to take part, we will give you specific details of

who to contact if you experience any negative effects relating to any aspect of this study and resources that might be helpful if that is the case.

However, in the unlikely event that something does go wrong, or you are injured during the research, due to negligence on the part of UCL or the NHS then compensation may be available. We recommend you discuss this with a member of the research team first as they may be able to help you with this. You would then need to please make this claim in writing to Prof. John King at UCL, who is leading the research, who would then pass the claim to UCL's insurers. Please note that you may have to bear the costs of the legal action initially, therefore we advise you seek legal advice about this.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated by members of staff as part of your participation in the research, there are NHS or UCL complaints mechanisms available to you. You can speak to Prof. John King at UCL, who is leading the research. You can also make a complaint to the Trust's Advice and Complaint Service (formerly the Patient Advice and Liaison Service). You can find more details about this here: https://www.candi.nhs.uk/service-users-and-carers/advice-and-complaints-service (email: feedback@candi.nhs.uk, tel: 020 3317 7102).

7 Who can I contact for further information?

Please feel free to contact Emma Jayne Kilford, who is organising and co-ordinating the study, if you have any questions or would like any further information about this study. You can contact her at:

Email: emma.kilford2@candi.nhs.uk. Tel: 020 7679 5774
Address: UCL Research Department of Clinical, Educational and Health Psychology, 1-19 Torrington Place, London WC1E 7HB

Thank you for taking the time to read this information and consider taking part in this research study.

We hope that you now have all the information you need to help make your decision about taking part. However, if you have any further questions about it then please do not hesitate to contact us to discuss any queries you might have.