INFORMATION SHEET

Title of project:

Online peer support in long-term conditions: A feasibility randomised controlled trial

We would like to invite you to participate in this research project led by King's College London (KCL) which is focusing on testing an online peer support platform to improve the lives of those living with long-term physical conditions. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. You may also wish to tell your GP that you are taking part in our research or share this information with your GP. The research team will *not* contact your GP *at any time.* Please contact the research team (email commonground@kcl.ac.uk) if you have any questions.

What is the purpose of the research?

In England, there is limited support for people living with long-term physical health conditions (LTC) to help them manage their mental well-being. We would like to change this. Researchers from King's College London, software developers, and a group of people living with LTCs, have co-designed a new intervention to help patients manage low mood and depressive symptoms.

The intervention is an online peer support platform with educational self-help resources. The intervention is exclusively for people with LTCs, regardless of their specific condition, meaning that all diagnoses are welcome, from diabetes to COPD, or arthritis to endometriosis.

The research aims to investigate what people think about our new intervention, including what they like and dislike. We also want to compare our new intervention to the generic NHS "Mental Health" webpage resources.

Why have I been invited to take part?

You may have been given this information by your healthcare professional(s), have been contacted by our research team, or heard about our study elsewhere and wanted to know more. We are inviting adults living with a long-term physical health condition(s) who have internet access to take part. We are not recruiting anyone who has a severe mental illness (bipolar disorder, schizophrenia, post-traumatic stress disorder, and/or psychosis, and or a diagnosis of dementia). You must be over 18 years of age and be able to speak and understand English.

We are aiming to recruit between 100-200 people for our study who will be randomly allocated to either access our new peer support intervention or form our control group. There will also be a third group who are part of a community engagement study who will

also be given access to the new peer support platform. If you choose to participate, you will be told which group you are part of and provided with further information at that time.

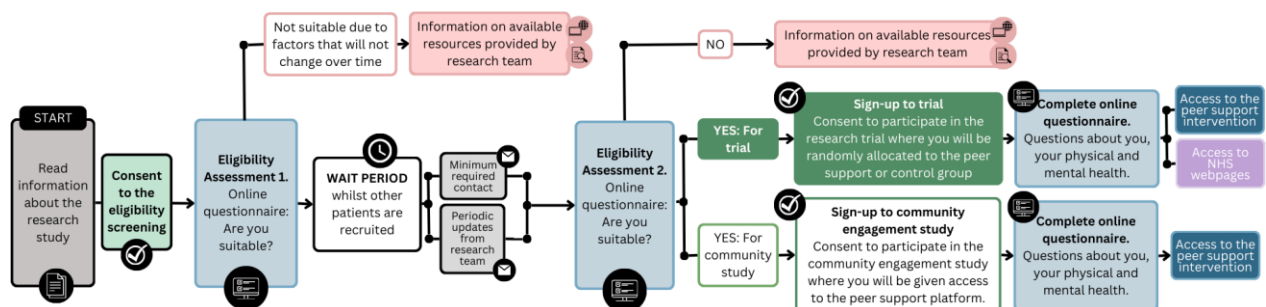**What will happen if I take part in this research?**

If you choose to take part in the project, the following will happen:

- **You will answer some questions that assess whether you are suitable for our research**, and you will be asked to provide consent to complete these eligibility screenings (15 mins).
- You can complete the screening by visiting the following link: https://bit.ly/commongroundresearch Please note that completing the eligibility screening(s) does **not** guarantee that you will be able to take part in our research.
- There might be **a delay between when your first express interest in our study, and when we are ready to start the trial.** This is so we can recruit enough people so that the online community is large enough for group discussions to form.
- **When we are ready to start the research trial, you will complete a short online questionnaire** (the second eligibility screening, 10 mins) to check you are still able to take part.

The research team tell you either:

- [1] That you are **suitable to take part** in our research and will be asked to provide consent if still interested in taking part
- [2] That you are **not able to participate**. Our team will provide information on other resources that might be suitable for you.

- If you are suitable to take part, **you will then be provided with more information and the opportunity to consent to participating** (10 mins). You will then be asked to **complete an online questionnaire** about yourself, your mental and physical health that should take approximately 10 minutes to complete.

The image below shows these first stages, from reading this information sheet to finding out if you are able to participate and signing up to the research. For an enlarged image, please click the PDF "Participant timeline: From reading the study information to finding out if you are able to participate in our research" on the previous page.

- Next, our research team will tell you **which group you have been allocated to**:
  - The intervention group: Our new peer support platform (either via main trial group or community engagement group).
  - The control group: NHS Mental Health webpages

During the study, we will ask you to also continue with your usual healthcare alongside taking part in the study.

If you are allocated to our new intervention (CommonGround), you will be given access to our online peer support platform where you can create your own anonymous profile, ask questions, share your experiences, react to and comment on other people's posts, and access self-help resources about living with an LTC. You can choose how much you use CommonGround during the three-month trial. You may receive emails with updates about what is happening on the platform. We will collect data about how you are using the platform, for example how often you log in and how many posts you make. You will be anonymous to other participants on the platform. However, our research team will be able to link your anonymous username to your personal details if required. You will have access to the platform for three months, after this time, the platform will become inactive, and your account will be closed.
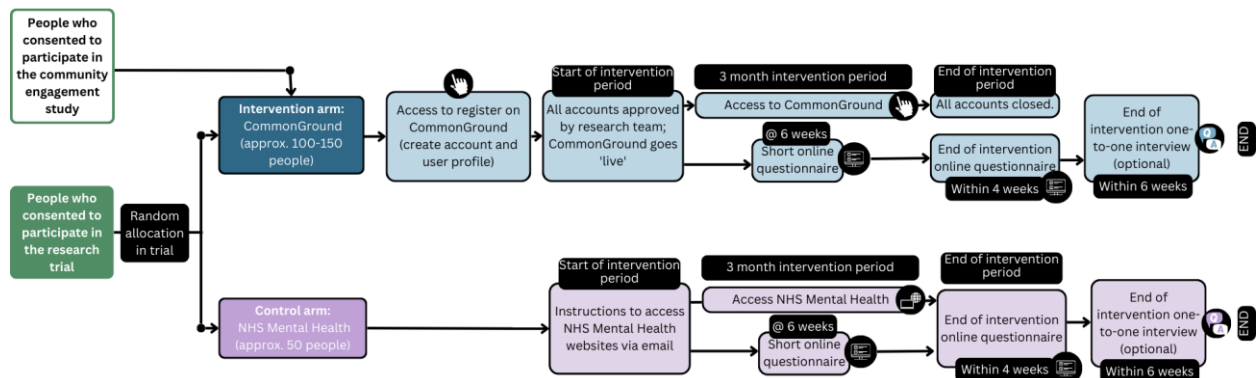
If you are allocated to our control group (NHS "Mental Health" webpages), you will be invited to access the NHS "Mental Health" webpages. You can choose how you engage with these resources, which one(s) you decide to access, and how frequently you access them. You may receive email updates from our research team.

We will also ask you to **complete some questionnaires during the three months** the trial runs for:

- A **short online questionnaire** (20 mins) halfway through (i.e., at approx. 6 weeks)
- The **final online questionnaire** at the end of the trial about your mental and physical health, and your opinions on the online peer support platform or NHS webpages (~60 mins)
- An *optional* one-to-one interview (usually virtual) to explore your views of the intervention and participating in the research more generally (approximately 60-90 minutes).

In total, participation in our study will take approximately 7-9 months, dependent on how quickly people sign-up to our research and whether you participate in an interview.

The image below shows the timeline from consenting to the three-month trial period through to the end. For an enlarged image, please click the PDF "Participant timeline: From consenting to our research to end of study" on the previous page.

Do I have to take part?

No, it is your choice and participation is completely voluntary. You should only take part if you want to. Choosing not to take part will not affect your medical care or legal rights and will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part (via email commonground@kcl.ac.uk (Phone or video chat available upon request). If you decide to take part we will ask you to sign a consent form.

What are the possible benefits of taking part?

As a token of our appreciation, we will offer shopping vouchers at the following stages:

- After you have completed the eligibility screenings **and** the questionnaires at the beginning of the trial (£10).
- After completing the final questionnaire (end of trial; £10)
- After completing the interview (if you are invited; £20).

There are no other direct benefits of participating. However, by participating you are helping us develop an intervention that aims to improve the lives of people living with LTCs. Your contributions to this project will be included in published research, though no identifiable information will be included.

Participating in this study will not necessarily improve your life or mental well-being. However, you may find the self-help resources useful. Also, if you are given access to our peer support platform, you may find the community supportive.

What are the possible risks of taking part?

Choosing to participate in this study does not guarantee that you will get access to our new intervention. Allocation to either the intervention group or the control group is randomly generated by a computer for those in the main trial. The research team cannot decide what group you will be in.

Some of the NHS "Mental Health" webpages topics might be distressing or difficult to learn about. You can choose to stop engaging with the resources at any time. The research team will periodically share information on how to access further support if you need it.

Some of the topics of the educational resources and those discussed on CommonGround might be distressing or difficult to read or learn about. Sharing your experiences and feelings can be a positive experience, but it can also be distressing at times. We cannot predict what people will talk about or share, and it might be that people discuss sensitive or potentially distressing topics. You have no obligation to engage with any content or respond to anyone – you are free to choose what you share and how frequently you wish to engage. If you need to, you can choose to stop engaging with CommonGround at any time and visit the "Further Support and Crisis" page on the platform to get additional support. This page contains information that will help and contact information of organisations who are available to provide this support.

It is important to remember that CommonGround **is not a crisis support service,** will **not be monitored 24/7** and **we will not be able to complete welfare checks.** On CommonGround, we are unable to provide one-to-one or emergency support for community members who are in crisis or need urgent help. If you are in an emergency situation, in immediate danger or unable to keep yourself safe, please call 999 or call NHS 111 for non-urgent medical advice and information. **There is the risk that someone might appear in crisis or disclose something concerning on the platform.** The peer support platform will be moderated following a Moderation Policy and Safeguarding Policy (you can read these if given access to the platform). These policies outline how we keep CommonGround safe and our obligations to notify the authorities under exceptional circumstances (e.g., welfare concern of a child or vulnerable adult, disclosure of criminal activity). Once again, while our moderators will be looking out for safeguarding concerns, it is important to remember that CommonGround **is not a crisis support service** and will **not be monitored 24/7** and **we will not be able to complete welfare checks.**

As for discussions between people in real life, online discussions have the potential to escalate, become confrontational or disrespectful, or upset someone. Everyone is invited to agree to a set of Community Principles ('terms of use') when they join the platform, and the platform will be moderated according to these principles by a team of moderators. The Moderation Policy and Community Principles reduce the risk of discussions escalating negatively, and you can find more support on our Further Support and Crisis page if needed. There are also 'flag this post to the moderators' and 'mute this user' features that you can use.

As with any social media platform or website, there is a small chance of hacking. The risk of CommonGround being hacked is no greater than the risk of any other site you use being hacked. The CommonGround website has been developed and maintained by our software developers (BitJam) who are Cyber Essentials Plus verified. Their systems ensure 24/7 data protection to keep the platform very secure. Data relating to how you use CommonGround will be collected and stored by BitJam under instructions from King's College London. The data will be encrypted (scrambled), which makes the data unreadable if the server is ever compromised, mitigating any risk to you in the unlikely event of hacking. While there is also

a risk that someone could attempt to upload a malicious attachment to the platform forum, all attachments are reviewed by our research team before they are shared.

There is the risk that someone's profile could be hacked and used maliciously. All accounts must be approved by the research team to ensure that they are legitimate participants. We also have two-factor authentication during login to reduce the likelihood of someone being able to gain access to an account that they do not own.

If you participate in an interview, you might find talking about your mental or physical health, life experiences, or experiences of using the interventions difficult. Interviews can be stopped at any time and you can choose to share as much as you like.

Who is funding and organising the study?

This project is being funded by King's Health Partners and Guy's and St Thomas Charity from the Multiple Long Term Conditions Challenge Fund. This project is sponsored and organised by King's College London.

Who has reviewed this study?

To protect your interests our research has been reviewed by an independent group of people, called a Research Ethics Committee. This project had been reviewed by South Central - Oxford C Research Ethics Committee (IRAS ID 328175).

How will we use information about you?

We will need to use information from you for this research project. This information will include your name, contact details, and demographic information. People will use this information to do the research or to check your records to make sure that the research is being done properly. 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 code 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.

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 the information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. 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.

Where can you find out more about how your information is used?

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

- At www.hra.nhs.uk/information-about-patients/
- Our leaflet available from www.kcl.ac.uk/research/support/rgei/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research or via www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to commonground@kcl.ac.uk or by requesting a video or phone call.

What else do I need to know about my data?

King's College London has a responsibility to keep information collected about you safe and secure, and to ensure the integrity of research data. **King's College London** will be the data controller, which means that we **are responsible for looking after your information and using it properly.** Specialist teams within King's College London continually assess and ensure that data is held in the most appropriate and secure way. **Your data will be retained for 7 years** in line with KCL Data Retention Policy. Your data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation and the Data Protection Act 2018). You can find out more about how we use your information by contacting the research team at KCL directly (commonground@kcl.ac.uk).

We will use the **minimum personally identifiable information possible during this study**. This information will include your name and contact details. The research team may use this information to contact you if needed for study updates, welfare, and safeguarding reasons, and in the unlikely case of an emergency. The only people in King's College London who will have access to information that identifies you will be people who need to contact you to check on your progress throughout the study or audit the data collection process. If you are given access to the platform, our software developers (BitJam) who host the platform will also have access to the personal information that you provide when creating an account, the content that you share, and data on how you use the platform. This information will be encrypted (scrambled) so that only the research team and BitJam can see it. The personally identifiable data that you enter via our online questionnaires will also be stored using our management software (Qualtrics). This data will be extracted from Qualtrics and stored on secure KCL servers and given a unique study ID (as described below).

Your name and contact details will not be visible to other people who may need to look at anonymised data (e.g., data analyst). **To maintain your anonymity and keep all your information secure, your name will be replaced with a code** (a unique study ID). The file that links this unique code and your personal details will be password-protected, held separately from all other data, and will only be accessible to the immediate research team. The linkage of your unique code and personal information will also be stored on secure BitJam or 3rd party servers (for those using the CommonGround platform). These servers are separate to any questionnaires or interview data that you provide. Any data that is transferred will use your unique, non-identifiable code. Your de-identified data will be securely stored on servers managed by King's College London, and also on 3rd party servers, which can provide additional security and backup. All the information we collect from you is strictly confidential. There are some instances where the researcher might be obliged to break confidentiality due to the nature of the disclosure being made (e.g., criminal activity) or safeguarding concerns.

If you participate in an interview to tell us about your experiences of participating, the **interview recordings will be sent to external transcribers** (e.g. Way with Words) who will be asked to sign a non-disclosure agreement before listening to any of the recordings. All recordings will be directly uploaded, to a secure location via their website. Transcripts of these recordings will be completed by Way With Words and downloaded by the research team via this secure location also. All identifying information will be removed from the final

transcripts that will be stored on secure password-protected King's College London servers. Direct quotes from your interview may be used in publications but these will be anonymised and not include anything that makes you identifiable. All personal and de-identified data will be stored in a secure, password-protected electronic drives.

The information that you provide us with during this research study may be used to support other research projects. Researchers in KCL or other organisations (for example, NHS organisations, universities, and other research companies) may request us to share your anonymous data. The research team will extensively review these requests and if approved, will share your anonymous data with them. You will not be identifiable in this data or in any research outputs that the requesting organisation produces. More information can also be found by following think link: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/

What will happen to the results of the project?

The results of our research will be summarised as a scientific article in an academic journal, presented at internal/external conferences/events/reports, presented within KCL research teams, and via publication on websites or other suitable publication avenues. You will not be identifiable in any report, publication, or presentation. We will write our reports in a way that no one can work out that you took part in the study. Our analyses will inform the next stages of our research, where we will test our intervention with a larger group of patients. After the trial has ended you can track any study updates or findings on our webpage [link].

What if there is a problem?

If you have a concern, about any aspect of this study, you should speak to the researchers who will do their best to answer your questions [Trial Manager: Dr Grace Lavelle (grace.lavelle@kcl.ac.uk)]. You may also contact the Patient Advice and Liaison Service (PALS) team at kch-tr.palsdh@nhs.net, or the King's College London Research Governance Office: rgo@kcl.ac.uk.

In the event that something does go wrong, and you are harmed during the research, then you may have grounds for legal action for compensation against King's College London but you may have to pay your legal costs. King's College London maintains adequate insurance to cover any liabilities arising from the study.

Who should I contact for further information?
If you have any questions or require more information about this project, please do not hesitate to contact us.

Hannah Grace Jones (Research Assistant at KCL)	**Dr Grace Lavelle (Research Fellow at KCL)**
Email: commonground@kcl.ac.uk	**Email:** commonground@kcl.ac.uk
Phone: Phone or video chat available upon request.	**Phone:** Phone or video chat available upon request

Thank you for taking the time to read this information and for considering taking part in our research.

If you wish to participate, **you can now complete the screening by visiting the following link**: https://bit.ly/commongroundresearch