**UpLift-X Trial: Patient Information Sheet**

**Brief Summary**

Patients who are referred for Cognitive Behavioural Therapy (CBT) in NHS Talking Therapies Services are being invited to take part in this study called UpLift-X. Patients who agree to participate will be offered an online group therapy called “UpLift Your Life”, which is based on CBT. This group therapy helps patients to learn and practise several coping skills. Participants will attend group therapy sessions once per week through a video call. Participants will also have access to an App with lots of helpful information about coping skills to recover from mental health problems. The group therapy will be delivered by experienced and qualified therapists working in the NHS service you were referred to. The therapists involved in this study will be delivering five different versions of this group therapy. All five versions cover the same coping skills, but in a different order. If you agree to participate, you will be randomly assigned to one of the 5 versions of the group therapy.

Choosing this treatment will not disadvantage you from receiving further treatment from the service if you need it. The study will just ask you some questions about your current problems and track whether the therapy works for you. We will only use information that we need to manage the study. We will let very few researchers know your name or contact details, and only to enable the research team to stay in touch with you and offer guidance and information for a limited period of time. We will make sure no-one can work out who you are from the reports we write.

Taking part in the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you and your treatment. This information sheet explains what this study is about and how your information will be used.

**What is the study about?**

People with mental health problems can access psychological therapies in the NHS. Previous research shows that group therapy is helpful and effective for a wide variety of mental health problems, and it can help more people to receive treatment more quickly, as it reduces waiting times for individual therapy.

We are offering a new form of Cognitive Behavioural Therapy (CBT) that combines an online therapy group via video call, and also an internet-enabled application (App) that has helpful videos and information about coping skills. The App will help you get the most out of the group by helping you to prepare for sessions, learn skills and practice them at home. You can access the UpLift Your Life therapy and App using your phone or a computer. The sessions will be delivered by a qualified NHS therapist and will take place once a week for 12 weeks. Each session will last for 90 minutes, at a fixed day and time each week. The patients attending the group therapy will have similar kinds of problems and symptoms. Based on previous studies, we think this group therapy will be effective and will help patients to get help sooner by reducing their waiting time and it will enable them to learn from others.

In this study we are interested in understanding the best way to deliver this therapy. To achieve this, we are running a clinical trial where the online group treatment will be delivered in 5 different versions. All five versions cover the same coping skills, but in a different order. We want to understand if some patients might benefit more from specific coping skills, and whether or not the order in which the skills are covered makes a difference to patients’ symptoms and mood. If you agree to participate, you will be randomly assigned to one of the 5 versions of the group therapy.

Taking part will not stop you receiving further treatment from the service if you need it.

**What does taking part involve?**

If you want to be involved in the study, you will need to provide consent by completing the online informed consent form on the next page. You will then be asked to complete an online survey about your mental health and how your current problems are affecting different areas of your life. This should take about 15-20 minutes to complete. It is very important that you complete all the questions, so that we can meet the objectives of the study. Your answers to these questions will potentially help us to learn how to personalise the group therapy to make it as helpful as possible for NHS patients.

A member of the research team will contact you by email to book you onto a treatment group and to access the App so you can view information to help you prepare for the start of your therapy. Once you start treatment, we will collect information about your treatment progress using the App. Before every group therapy session, you will receive a notification from the App to complete some questions about your symptoms that week. The therapist will review your responses every week. In this way, we will monitor how you are feeling and how the therapy is working for you and other patients. The group therapy sessions may be video recorded so we can evaluate the competency of the therapist facilitating the group to provide them with feedback to ensure you get the best possible treatment. The focus of the recording is on what the therapist is saying and doing, not the patients in the group. After 3 and 6 months, we will also ask you to provide some information about your mental health and use of other services using an online survey to see how you got on after your therapy. It is important that we collect this information even if you don’t start or complete your treatment. It will help us find out the best way to deliver this treatment in the NHS.

We might also contact you to take part in an optional study. This will ask you about your views about the online group therapy and the App.

You will be asked to fill in an online consent form, tell us your contact details and complete a set of questionnaires about your mental health. This should take about 20 minutes.

**What?**

**Where?**

Online survey

You will be contacted with information about how to register for your online treatment group. You will have access to information and videos to help you get the most out of therapy.

Online therapy platform

**When?**

Now

In 2-8 weeks

You will attend 12 group therapy sessions via your computer or phone. These will take place once a week and will last for 90 minutes. Two days before each session you will be sent a text reminder to complete a short questionnaire about how you have been feeling that week.

Online therapy platform

For 12 weeks

When you have finished treatment, you will be sent a set of questionnaires to complete online to see how treatment has worked for you.

You will be sent a final set of questionnaires to complete online to see how you have got on after your therapy.

Online survey

Online survey

In 3-5 months time

In 6-8 months time

**Why have I been asked to take part?**

You have been referred for Cognitive Behavioural Therapy (CBT) in the NHS Talking Therapies service, which means you could benefit from accessing a group-based version of this type of treatment. You have the opportunity to take part in the study and receive this new online group therapy enhanced by a supporting App. If you have any questions about the information provided here, you can contact [insert local research assistant email/phone] to find out more before deciding if you want to take part.

**Do I have to take part?**

No, you do not have to take part. You can refuse to take part without any consequences to your treatment in the service. If you choose not to be involved, you do not need to do anything else as you will remain on the waiting list for CBT.

**What are the possible benefits of taking part?**

One of the most common concerns for patients with mental health problems is how long they will have to wait for therapy. By taking part in the study, you will be able to quickly access a new online group therapy that is relevant for a wide variety of mental health problems. This will mean you can attend treatment in a way that is most convenient to you, without a need to travel to an NHS location. You can benefit from the mutual support and learning that occurs in group therapy, where problems are normalised and useful coping skills and tips are shared between members. You will also have access to the App to support your treatment. You will also help us to learn how we can make this intervention as helpful as possible for different individuals and potentially offer psychological treatments more quickly in the future.

**What are the possible disadvantages and risks of taking part?**

We do not expect that taking part in the study will lead to any disadvantages or risks to patients, by comparison to the usual CBT treatment that you have been referred to. The coping skills that will be covered in all 5 versions of the group therapy have previously been shown to be safe and effective in other studies. If you do not feel better after taking part in the study, you can receive further support from the NHS Talking Therapies Service. However, we do recognise that mental health is an area which is personal and sensitive for everyone. As with any therapy, there will be discussion of difficult topics that may be upsetting. However, the aim is it to improve these areas through therapy. Furthermore, some people may have worries about their confidentiality and anonymity when getting involved in group therapy. Because of this, we will ensure all group participants abide by a confidentiality agreement, preventing anyone to share any information that comes up in the group therapy with anyone else. You will have the option to share enable or disable your video camera, and to modify the name that appears in the group session, if that makes you feel more comfortable.

**How will we use information about you?**

We will need to use information from you and your treatment for this study. Rotherham Doncaster and South Humber (RDASH) NHS Foundation Trust is the sponsor of the study and will act as the Data Controller. This means that they are responsible for looking after your information and using it properly. This information will include your:

• Name • Contact Details • Employment status • Ethnicity

• Age • Gender •Self-reported disabilities •Mental health symptoms

The research team will collect the data using secure industry-standard electronic platforms. This means we will keep all information about you safe and secure. People will use this information to do the research or to check 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 patient ID code instead. No one outside of your care team will be able to link the information you provide for the trial to your health record. Information will not be combined with other information in a way that could identify individuals. The information will only be used for the purpose of the healthcare research and cannot be used to contact or affect the care of any individuals. It will not be used to make decisions about future services available to you.

Recorded group therapy sessions will be checked by a member of the research team who is a qualified, experienced and accredited NHS therapist to check how competently the therapy is being conducted. The recording will be unobtrusive and not obstruct the group. The sessions will be video recorded by the secure therapy App and recordings will be transferred to the NHS research team using a secure data transfer method. The recordings will be stored on a secure NHS Trust network drive only accessible by the research team to ensure all data is secure. The only reason to make these recordings is to ensure the therapy is being delivered to a high clinical standard.

Once we have finished the study, we will keep fully anonymised data for 10 years so we can check the results. We will not keep any identifiable information (e.g., names and contact details will be deleted from our database when the study ends). We will write our reports in a way that no-one can work out that you took part in the trial.

Information collected will only be accessible to members of the research team. The only exception to this is if the information leads us to be very concerned about your or someone else’s safety. In that case we would contact your GP or other health services to let them know.

The research team at the University of Sheffield will have access to all of the electronic data and personal information listed above, as they will lead on data analysis and the production of reports and publications. Some of your anonymised data (numerical responses to questionnaires, without any identifiable information) will also be sent to a member of the research team in Canada, as he is an expert in statistical analysis and will help us to work out the results. Your information will be kept safe and secure during this process, using industry-standard network drives that are not accessible to anyone outside of the research team.

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. Anonymised data saved from this trial may be shared with other researchers and used in future research. This is considered good practice in open and transparent scientific research.

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

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

• at [http://www.hra.nhs.uk/information-about-patients/](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/)

• by asking one of the research team using the details at the end of this sheet

If you have any concerns of questions about your data in this study, you can contact the RDASH NHS Trust Data Protection (DPO) officer (Caroline Britten, Email: rdash.dpo@nhs.net).

**Can I change my mind and opt-out of the study later on?**

Yes, you can withdraw from the study at any time without any consequences to your care in the service, and you do not have to give a reason. We will normally keep the anonymised information about you that we already have, but not contact you in the future, or gather more information after that point. If you specifically ask us to, we will remove all data we hold of you if it is feasible to do so. If you request for your data to be deleted after the last data collection, it will not be possible for participants to withdraw, because the data collected will be anonymized and it may not be possible to identify your specific data. If you wish to withdraw from the research, please use the contact details of the Trial Manager at the end of this form.

**Safeguarding**

If you wish to discuss the study or make a complaint in the first instance, you can contact the Chief Investigator (contact details below) or the Grounded Research Team (Email: rdash.groundedresearch@nhs.net, Phone 03000 212 456). However, we understand that you may not always feel comfortable doing this therefore, you can contact the Patient Advice and Liaison Service, who can support you by contacting the service on your behalf. PALS can be contacted on telephone number 0800 015 4334, email:  rdash.pals@nhs.net, or address: Rotherham Doncaster and South Humber NHS Foundation Trust, Woodfield House, Tickhill Road Site, Tickhill Road, Balby, Doncaster, DN4 8QN.

Alternatively, to raise a complaint you can contact the RDASH Patient Safety and Investigation Team: Telephone: 07967793306 during normal office hours, Monday to Friday (excluding public bank holidays). Email: rdash.complaints@nhs.net. For further online information, you may access the website: <https://www.rdash.nhs.uk/policies/patient-advice-and-liaison-service-pals-policy/>

**Further Supporting Information**

**Does the study have ethical approval?**

This study was independently reviewed and approved by an NHS Research Ethics Committee (Ref: 24/YH/0182/IRAS ID 340528 [*Yorkshire & Humber – Sheffield Research Ethics Committee*]).

**What will happen to the data and the results of the research project?**

We will analyse clinical outcomes (depression and anxiety symptoms, functioning, quality of life). We will compare outcomes from the five versions of the group therapy and see if the order in which the coping skills are covered makes a difference to patients’ symptoms and mood. We will use the data to learn how we could recommend the most helpful coping skills to patients in a personalised way. We will also compare the effectiveness and costs of this group intervention to the usual CBT treatments that are offered in the NHS using anonymised electronic health records. We will provide a summary of results to participants by email once they are available, a written summary to the NHS Talking Therapies Service and we will share our results in scientific publications and presentations at conferences.

**Who is organising and funding the research?**

Rotherham, Doncaster and South Humber NHS Foundation Trust (RDaSH) have overall responsibility for running the trial. They are working in partnership with researchers at the University of Sheffield and MindLife, an industry partner who are developing the intervention and App. Innovate UK are funding the research. Patients with experience of using Talking Therapies services have helped inform the trial.

**Contact details**

If you would like to find out more, please visit the project website: <https://www.upliftyourlife.net/>

| **[Local NHS Site NHS-Talking Therapies] Research Team** |
| --- |
| **Principal Investigator**  | **Research Assistant** |
| <Name><Talking Therapies Team name> <Address><Telephone><Email> |  <Name><Talking Therapies Team name> <Address><Telephone><Email> |

| **Central Research Team** |
| --- |
| **Chief Investigator**  | **Trial Manager** |
| Jaime Delgadillo, PhDProfessor of Clinical PsychologyInstitute of Psychiatry, Psychology & NeuroscienceKing’s College London, 16 De Crespigny Park, London SE5 8AB, United Kingdomemail: jaime.delgadillo@kcl.ac.uk | Dr Ben Lorimer Grounded Research Team, RDaSH NHS Foundation Trust2 St Catherine’s Close, Tickhill Road Hospital site, Balby, Doncaster. DN4 8QNPhone 03000 212 456 Email – rdash.upliftx@nhs.net |

**Thank you for taking time to consider participating in this trial.**