Examining the feasibility and acceptability of a new crisis-planning intervention for those who have been sectioned under the Mental Health Act

INFORMATION FOR PARTICIPANTS

Finch Study Pilot Trial Staff Participants Interviews
Participant Information Sheet_V2_22/11/21

This information sheet is to let you know about a research study that you may be eligible to take part in if you wish. Before you decide, it is important that you understand why the research is being done and what it would involve for you. The researcher will go through the information sheet with you and answer any questions you have. You can also talk to others about the study if you wish, and please ask us if there is anything that is not clear.

This study has been reviewed by an NHS ethics committee to ensure that the rights, safety, dignity and well-being of everyone that takes part in this study are protected. [Insert REC reference here].

Principal Investigators

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What is the purpose of this study?

The number of people being involuntarily admitted to mental health hospitals under the Mental Health Act (being "sectioned") has been increasing in the UK. One way to try and reduce this number is to offer support to people who get sectioned to try and reduce the likelihood of it happening again in the future.

There has not been very much research carried out to understand what types of support might help stop or reduce the likelihood of people being sectioned. The aim of this study is to develop and test a new type of support that aims to reduce the likelihood of "sectioning" happening again once someone leaves hospital. The new type of support will involve developing a crisis plan and receiving regular contact from a psychologist over the next year to help people develop skills to manage their own mental health and respond if another crisis may be developing. In this study, we are particularly keen to include and consider how to help people from ethnic minority backgrounds as they are more likely to be "sectioned" compared to White British people.

You will either be a personal mental health worker delivering the new type of support to service users close to being discharged or a member of NHS staff working closely with a service user receiving the support. We would like to interview you about your experience of the new type of support and get your feedback on any ways we can further develop it moving forwards.

Why have I been given this information?

We are looking to interview as many personal mental health workers as possible who have been involved in delivering this support or staff supporting people who have been given the new type of support.

You have been given the information because you either have:

- Delivered the intervention to participants in this trial
- OR You work in an NHS mental health setting where the new intervention has been tested, for example, you may a care-coordinator, social worker, nurse or psychiatrist.

Do I have to take part?

No. Taking part in this research study is voluntary therefore it is up to you to decide whether or not to take part. You should not feel under any pressure to take part. If you do decide to take part, you will be asked to sign a consent form. Even after signing this form you will still be free to withdraw at any time and without giving a reason. This will not affect any care you may receive in the future.

What will happen to me if I take part?

If you choose to, you can meet a researcher for this study at a convenient location for you (or on the phone/using video-calling software) to discuss the interview in more detail. The researcher will talk through the pilot study, explaining the reasons for running this study and answering any questions you may have. If you are interested in taking part you will be asked to sign a consent form.

If you decide to participate in the study, we will invite you to an interview at a location of your convenience. The interview will take place either on the hospital ward on which you work, or via telephone/video-conferencing software. You will be able to choose which option suits you best. The interview should take up to about 60 minutes and will be carried out by a researcher.

The interview will be audio recorded, or video-recorded if you decide to have your camera on during an interview on an online video call. The video recording will be changed into a sound file before the interviews are transcribed. The researchers will anonymise your personal information in the transcript so that no one will be able to link it back to you.

The questions in the interview will be about your experience with the new type of support. We would like to know about parts of the intervention you felt were helpful, as well as those that were less helpful. We will ask you to share any feedback or ideas to improve the intervention moving forwards.

Will taking part in the study cost me anything?

No. The study will only involve your time.

How will we use information about you?

We will need to use information from you for this research project. This will include your name and contact details, and any data you give us through taking part in the interview. Everyone involved in this study will keep your data safe and secure. We will use study code numbers, rather than your name, to refer to you. This is to keep your name and any identifying details anonymous and confidential. We will also follow privacy rules.

Audio-recordings of your consent to take part in the study and your interviews will be separately and securely stored in the protected UCL online system. During the interview the interviewer will not use your full name to protect your identity.

The audio recording will be transcribed by a company approved by UCL which is compliant with General Data Protection regulations (GDPR). We will then remove anything that may identify you in the transcripts, to further protect your identity.

Digital and computer sound files will be destroyed within one month of the interviews being transcribed. The transcripts will be stored on the academic institution's computer as a password protected document and will be accessible by the UCL research team only. If the researchers would like to use a direct quote from you in a publication they will used the fake pseudonym, that is a fake name, or they may use the participant number. We will retain a sound file recording of you giving consent to take part in the interview securely, in line with UCL's data protection guidelines.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. You can choose to withdraw your data up until the point the interviews are analysed.
- 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.
- You can decide whether or not you would like your anonymised research data to be used by others at UCL for future research. This is completely optional.

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 [the ward or via email – m.birken@ucl.ac.uk]
- by asking one of the research team
- by sending an email to Dr Mary Birken, the senior study researcher – m.birken@ucl.ac.uk
- by sending an email to data-protection@ucl.ac.uk

The data custodian for this study is Professor Sonia Johnson.

What are the advantages and disadvantages of taking part?

Taking part in this study will help us to evaluate a new crisis-planning type of support. Your feedback will help us to understand more about how the new type of support worked in practice and whether it was seen as useful and acceptable.

During the intervention, you will be asked to reflect on the crisis-planning sessions you have delivered or heard about through a patient and provide feedback on how they went and any improvements you would recommend. If you would like to stop the interview for any reason, you can do so at any point and request your data be withdrawn (up until it is analysed).

What happens if something goes wrong?

We will do our best to keep all information that you give us confidential. In a rare situation where we felt that you had disclosed to us something that suggested someone else was at serious risk of harm, abuse or neglect, we will need to consider passing this on even if you have not agreed to this. This would normally be to your NHS Trust, though there could be rare situations where risk was immediate enough for us to contact the police or emergency services.

It is necessary for us to point out that if you were to feel that taking part in this research project caused you upset or harm, there are no arrangements in place for offering compensation.

However, if you have any concerns about the way you have been treated during the course of the research, the researcher will be very happy to discuss this with you. You could also contact the Chief Investigators, whose contact details are above. If you wish to complain formally, or have any unresolved concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact your local NHS Advice and Complaints Service:

Advice and Complaints Service
[**To be updated based on location** Camden and Islington NHS Foundation Trust
FREEPOST 1st Class (LON 12613)
London
NW1 0YT
Tel: 020 3317 3117
E-mail: complaints@candi.nhs.uk]

Minor Complaints

If you take part in this project and later have a minor complaint then please contact Mary Birken in the first instance: m.birken@ucl.ac.uk

Formal Complaints

If you continue to have concerns, please contact Professor Sonia Johnson, the Principal Researcher of this project: s.johnson@ucl.ac.uk . If you are still not satisfied, complaints may ultimately be referred the NHS Trust's complaints team at [Insert local trust's complaints team details].

Independent Advice

If you would like to talk to someone independent about your participation in the study, you can get in touch with your local NHS Research & Development office. [insert local R&D office contact details here]

Local Data Protection Privacy Notice

The controller for this project will be University College London (UCL). The UCL Data Protection Officer provides oversight of UCL activities involving the processing of personal data, and can be contacted at data-protection@ucl.ac.uk. This 'local' privacy notice sets out the information that applies to this particular study. Further information on how UCL uses participant information can be found in our 'general' privacy notice. For participants in research studies, click here: https://www.ucl.ac.uk/legal-services/privacy/ucl-general-research-participant-privacy-notice

The information that is required to be provided to participants under data protection legislation (GDPR and DPA 2018) is provided across both the 'local' and 'general' privacy notices.

The categories of personal data used will be as follows:

- Name (on consent form only)
- Address to send report if wished
- Gender
- Age
- Ethnicity

The lawful basis that will be used to process your personal data are: 'Public task' for personal data and 'Research purposes' for special category data. Your personal data will be processed so long as it is required for the research project. We will endeavour to minimise the processing of personal data wherever possible. If you are concerned about how your personal data is being processed, or if you would like to contact us about your rights, please contact UCL in the first instance at data-protection@ucl.ac.uk.

What is the next step?

If you would like to take part, please contact the study team via our email address: dop.finch@ucl.ac.uk

Thank you for reading this information sheet.