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 Service Users Pilot Trial Interviews_V2_22/11/21

This information sheet is to let you know about a research study that you may be able 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. This new type of support will involve developing a crisis plan and 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.

As you have been receiving the new type of support, we would like to interview you to learn more about how you have found it, and to get your suggestions for improving it moving forwards.

Why have I been given this information?

You have been given this information because you have taken part in the FINCH research study and were allocated to receive the new crisis planning support in addition to your usual care. The research team would now like to hear about your experience of receiving this new type of support.

Do I have to take part?

No. Taking part in this interview is voluntary therefore it is up to you to decide whether or not to take part. There is no obligation for you to take part and if you decide not to take part, this will have no effect on your current care and support from health and social care services. 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 happens next if I am interested in taking part?

If you would like, you can meet a researcher for this study at a convenient location for you to discuss the interview in more detail (or speak over the phone or video call). The researcher can talk through the interview, explaining the reasons for running this interview and answering any questions you may have. If you decide you do want to take part, you will be asked to sign a consent form, or confirm your consent to take part in a videocall.

The following section will explain what will happen in the study if you choose to take part.

What will happen if I take part?

We will invite you to an interview lasting up to about 60 minutes. The interview will take place at a location which is most convenient to you. Therefore, the interview may be conducted remotely (over the phone or using video-calling software), at your local community mental health service or at your home address.

Each interview will usually be carried out by a researcher with lived experience of mental health conditions who is also a member of the research team, with a second researcher present to record the interview.

The interview will be about your experience receiving the crisis-planning support, specifically about things that you have found helpful and unhelpful about it. We will talk about your experiences since being discharged from hospital and the factors that have impacted your well-being. We will also ask about your ideas for improving the support for other people in the future.

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 (typed up word for word). When the researchers transcribe this recording, they will anonymise your personal information so that no one will be able to link it back to you.

To thank you for your time in the study you will receive a £20 voucher as a token of appreciation.

Will taking part in the study cost me anything?

No. The study will only involve your time.

Who will know I am participating in the study?

Other people involved in your care such as your Consultant Psychiatrist and Care Coordinator will be informed that you are participating in this interview as we will record it on your clinical notes. This is to ensure your wider care team are updated about your research involvement. We will also send a letter to your GP to inform them about your participation in the study.

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 (on consent form only)
- Address to send report if wished,
- Gender
- Age
- Ethnicity
- Education
- Housing Status
- Living Situation
- Marital Status
- Sexual Orientation
- Employment Status
- Mental Health Diagnosis
- Any experiences or opinions discussed in the interview

People will use this information to do the research or to check your records to make sure that the research is being done properly.

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 keep all information about you safe and secure.

Audio-recordings of your consent to take part in the study and your interview 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 point, without having to give a reason. If you stop, we will keep the information you have already provided for the study, unless you tell us you don't want us to. If you withdraw from the study more than two weeks after your interview, we will have already transcribed and anonymised your interview and will not be able to stop using it after this point.
- 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 interview will help us to understand more about the effects of the new type of support. You might find sharing your experiences and feedback on the new type of support to be worthwhile.

To thank you for your time in the study you will receive a £20 in vouchers as a token of appreciation.

You might find it upsetting to share your experiences of receiving this new support and about your experiences following discharge from hospital. The researcher will be sensitive to your needs and will offer breaks throughout the interview as you need. You are free to stop the interview at any time without giving a reason and this will not affect the on-going care you are currently receiving.

What happens if something goes wrong?

This project does not have any medical interventions such as asking you to take a new medication. If you choose to participate, we will ask you to participate in an interview.

We will do our best to keep all information that you give us confidential, However, if we obtain information that makes the research team concerned that there is a significant risk to you or someone else (including the study researchers) we will need to consider passing this on even if you have not agreed to this. Usually we would communicate this to NHS mental health services or your GP. In a rare situation where we felt there was an imminent risk of significant harm to someone else, we may need to contact 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:

[**To be updated based on location**

Advice and Complaints Service

Camden and Islington NHS Foundation Trust

FREEPOST 1st Class (LON 12613)

London

NW1 0YT

Tel: 020 3317 3117 E-mail: complaints@candi.nhs.uk]

If at any point during the study you disclose any information that relates to yourself or someone else being at risk, we would inform your clinical team.

What happens if I lose the ability to make informed choices (capacity) about the research during the study?

If it becomes apparent to the researcher during the interview that you are not fully understanding what is happening and aren't able to make an informed choice about taking part in the study, the researcher will stop the interview, and all information you have provided up to this point will be withdrawn from the study.

Minor Complaints

If you take part in this project and later have a minor complaint or an issue you want to raise with the research team, 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 independent advice about taking part in research please contact your local Patient Advice and Liaison Service (PALS). You can get in touch with your local PALS by [insert local PALS 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
- Education
- Housing Status
- Living Situation
- Marital Status
- Sexual Orientation
- Employment Status
- Mental Health Diagnosis

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 or to get more information about the study, please contact the study team via our email address: dop.finch@ucl.ac.uk or please speak to your key worker.

Thank you for reading this information sheet.