INFORMATION SHEET FOR THE COMMUNITY NAVIGATOR STUDY
FEASIBILITY TRIAL

Version 2. 09/02/2017.

Study Title: Community Navigator Study. Feasibility trial of an intervention to increase community connections and reduce loneliness for people with complex anxiety or depression

You are being invited to take part in a research study. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

We are developing and testing a programme of support to improve community connections for people who have anxiety or depression and who are experiencing feelings of loneliness. A Community Navigator helps people to consider their current social contacts and social activities and then to develop a plan to engage with desired activities and begin building or strengthening relationships within their local community. The Community Navigators will also be running sessions where participants can meet, which people will be invited to attend. In this study, we will test whether support from a Community Navigator helps people to feel more connected to their social communities and less lonely, leading to an improvement in their wellbeing.
You are being asked to take part in this study as we would like to test if support from a Community Navigator is helpful for people. Your experiences of the programme of support will hopefully enable us to further develop the support and to try it out with a larger number of people in the future.

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

You have been asked to take part because you have been using one of the secondary mental health services participating in this study. You have also indicated to a member of staff in the service which has been supporting you that you were happy to discuss participating in the study with a researcher.

**Do I have to take part?**

It is completely up to you to decide whether or not you would like to take part. If you do not feel the study is relevant to you or you do not wish to increase your social connections, then you do not need to take part. If you decide to take part you will be asked to sign a consent form but you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive from mental health services now or in the future. If a researcher is unable to contact you for a follow-up interview, or if you decide you do not want to take part in a follow-up interview, the research team will continue to use information you have already provided and information from your patient records, unless you tell the research team or mental health staff involved in your care that you do not want this to happen.

**What will happen if I take part?**

Before your invitation to take part in the study is confirmed, a researcher will complete a brief questionnaire with you about how connected to others you feel. This questionnaire has six questions. To make sure the study includes people with similar levels of need for support with developing social connections, only people whose answers score in a certain range on this measure will be included in the study. If you were not offered the chance to take part in the study following this brief questionnaire, the researcher will offer to send you some information about
local community resources which may help with developing connections with others.

If you agree to take part in the study, you will be randomised into one of two groups, Group A or Group B. Randomised means that a computer will allocate you randomly (as if by the roll of a dice) to receive: either support from a Community Navigator in addition to the support you already receive from mental health services; or no additional support, but you would carry on receiving your current support from mental health services. Neither your doctor, nor the study team, nor you will choose which treatment you receive, and chance will decide who enters which group. You will be asked to participate in a research interview before you are allocated to a group and another interview about 6 months later (each interview lasting around 1 hour). These interviews will involve completing questionnaires about loneliness, social support, activity and mood. A researcher will also collect information from your NHS patient records including your diagnosis, care cluster, and use of community mental health and social care services. However this will not need your active involvement.

**Group A**

If you are allocated to Group A, you will be offered up to 10 meetings with a Community Navigator, over a 6 month period. This will be in addition to the support you already receive from mental health services. Your Community Navigator will firstly support you to think about your existing social network, and the current and potential support it provides; your existing strengths and interests and any potential areas where you feel new activity, social connection or support would be beneficial.

Together with your Community Navigator, you can develop and use an action plan to increase how connected you are to your community. Examples of the types of support you could receive include practical help to access an activity you choose, local knowledge of leisure activities, culture or social support groups. The navigator will have access to a small budget of £100 to help you access and participate in social activity and to develop network connections. The navigators are employed by the NHS. They have all received training and have supervision for this role.
The Community Navigators will also be running sessions open to everyone in Group A. There will be up to three meetings, alongside individual meetings with your Community Navigator, which will be a good chance to meet other people taking part in the programme. It will help you to understand more about this programme of support and give you a chance to share ideas about groups or activities that you enjoy.

If you are allocated to Group A, and receive support, you will be asked to provide feedback on two meetings with your Community Navigator. A researcher will contact you after these meetings and, if you agree to take part, ask you some questions over the phone. A researcher will also receive an anonymous account from your Community Navigator about what you are doing together in each of your meetings. No personal information will be included in this account, and you will not be identifiable from it. This phone call will take only five or ten minutes.

If you are in Group A, you may also be asked to take part in a third research interview. In this interview, we are looking to hear what works well about the programme and what isn’t working so well, so that we can continue to improve the programme. It is your choice whether to take part in the interview and whether to provide feedback on your meetings. If you decide not to take part, it will not affect your relationship or the services that you receive from your Community Navigator or mental health services.

**Group B**

If you are allocated to Group B, you will continue with your usual support and will be given some written information about local resources and community activities.
Taking Part in Community Navigator feasibility trial: What is involved?

1. Mental health staff will explain briefly about the study and ask if you would agree for a researcher to contact you to discuss taking part.

2. A researcher will tell you more about the study, answer any questions and send you an information sheet.

3. If you are still interested, the researcher will arrange to meet you, answer any further questions and take your written consent to take part.

4. If you consent, the researcher will complete an interview with you lasting about 1 hour, involving a number of questionnaires. You will be offered a gift of £20 for your time and help.

5. You will be allocated to either Group A or Group B.
   - **Group A** will be offered up to 10 sessions with a Community Navigator and 5 group sessions in addition to the care you are currently receiving from your mental health team.
   - **Group B** will receive care as usual but will receive written information about local resources and community activities.

6. The researcher will arrange to meet you again, six months after your first research interview. They will confirm your consent and then complete another research interview, lasting about 1 hour. You will be offered a gift of £20 for your time and help.

7. If you were allocated to **Group A**, a researcher may contact you to arrange an interview with you to explore in more detail how you experienced the support being offered. You will be offered a gift of £20 for your time and help.
What are the possible benefits of taking part?

We hope that having support from a Community Navigator will reduce feelings of loneliness and improve quality of life and health. Reading through the written information about local resources and community activities may also be useful. People in both groups will be involved in a study which will help to find out more about what kind of support is helpful for people with anxiety or depression who are experiencing feelings of loneliness. People in both groups will be offered a £20 cash gift for the initial and follow up research interviews. People allocated to Group A will be offered an additional £20 gift in cash if they take part in the final research interview exploring their experience of the support they received.

What are the possible disadvantages of taking part?

It is possible that you will not find receiving support from the Community Navigator or the written information about local resources helpful and this could be disappointing. Making a plan to engage more with people and activities in your community could be very useful but you may find it challenging. Making goals and feeling unable to meet them could be frustrating. However the goals you choose to make and the activities you decide to participate in will be completely led by you. If you do not wish to continue meeting the Community Navigator, you are free to stop meeting at any point.

If you have enjoyed meeting the Community Navigator and found their support useful, you may be disappointed when your meetings end after 10 sessions. They will discuss with you where you could access ongoing support or information about local organisations and services. We hope this will help make the ending of this support easier.

If you do not receive support from the Community Navigator as you were randomly allocated to the control group of the study, this could be disappointing. You will receive written information about local groups and activities which you may like to attend, and you could discuss this with your care coordinator or another member of staff from the service you use.
Will my participation be kept confidential?

The mental health service that is supporting you (CDAT/CCT) and your GP will know you are taking part in the study. Community Navigators will make brief notes on your meetings which will be included in your patient records.

All the information that is collected about you by the researchers during the three research interviews will be kept strictly confidential and anonymised. Following the final research interview, navigators will not be told what you individually have said, although we will give them overall feedback about what the people receiving the programme of support thought of it.

The only circumstances in which a researcher or Community Navigator would not maintain confidentiality is if you told them something which made them believe there was a serious risk to your or someone else’s safety. In those circumstances, they would discuss their concerns with staff at the service you have used, who would decide whether any further action was required.

Where can I get further information?

If you require any further information or have any questions not answered by this information sheet, or if you have any comments or concerns, please do not hesitate to contact a member of the research team. The research team representatives could be the researcher who is conducting the interview or:

Study Chief Investigators:

Professor Sonia Johnson  
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Tel: 020 7922 7871

What if I am unhappy with the research?

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
Camden and Islington NHS Foundation Trust
FREEPOST 1st Class (LON 12613)
London
NW1 0YT
Tel: 020 3317 3117
E-mail: complaints@candi.nhs.uk

What happens to the results of the research study?

The information collected will be made anonymous and written up in a report. The report will not contain any personal information from which you could be identified. During the study, the audio recording will be stored securely at the McPin Foundation, together with the typed transcript of your interview and any notes made by the researcher. At the end of the study, the audio recordings will be destroyed and interview notes and transcripts will be securely archived at UCL, in accordance with data protection policies. The results are likely also to be published in scientific journals and publications read by mental health service
Clinicians and service users. The results will also inform the development of this Community Navigator programme which could then be tested with a larger group of participants. If you are interested in the study, a copy of the report will be made available to all participants and other local service users.

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

The research is being managed by University College London. It is funded by the NHS National Institute for Health Research.

**Who has reviewed the study?**

This study has been reviewed by the East of England – Cambridge Central Research Ethics Committee and was approved on 26th July 2016 (REC reference 16/EE/0255).

Thank you for reading this information sheet