PRODIGY Final Report Supplementary Documents

Participant information sheets

A. Internal pilot PRODIGY Randomised Controlled Trial Participant Information Sheet (Version 3.0 18/01/2013):

[insert site-specific logos]

PRODIGY: Prevention of long term social disability amongst young people with emerging psychological difficulties: a pilot randomised controlled trial of social recovery cognitive behavioural therapy.

Participant Information Sheet

You have been given this information sheet because you are being invited to take part in a research project. It is up to you to decide whether or not you want to take part. Before you decide, it is important that you know about the project. This information sheet will tell you about why the project is being done and what will happen if you decide to take part. Please take as much time as you need to read and understand this information: you can talk about it with other people if you want. If there is anything you don't understand you can speak to a member of the PRODIGY team. You will find the team's contact details at the end of this information sheet.

Why is the project being done?

Some young people who experience psychological difficulties sometimes find it hard to carry on living the life they want to live: they might have problems going to school or college, finding a job or taking part in social activities. "Social recovery" is a term used to describe when someone is living the life they want to despite having experienced psychological difficulties. We think that people might make a better social recovery if they work with a therapist using a technique called Social Recovery Cognitive Behavioural Therapy (SRCBT for short). This research project is being done to see whether working with a therapist in this way can help people to make a better social recovery.

Why have I been invited to take part?

We are inviting young people receiving support from youth services in East Anglia and Manchester who are experiencing psychological difficulties and not spending much time doing structured

activities to take part in the project. Structured activities include things like work, education, childcare, housework, sport and leisure activities. If you are interested in taking part in the project we will ask you some questions about how you are spending your time at the moment to help us decide whether this project is right for you.

Do I have to take part?

No, it is up to you to decide whether or not you want to take part. If you do decide to take part you will be given this information sheet to keep and will also be asked to sign a consent form. Even if you decide to take part, you can change your mind at any time without having to give a reason. If you decide not to take part, or to stop taking part, this will not affect the standard of care you receive.

What is the therapy being tested?

The therapy being tested, Social Recovery Cognitive Behavioural Therapy (SRCBT), is a new talking therapy which aims to help individuals spend more time doing activities which are meaningful for them. During the therapy, the therapist works with the client to identify activities the client would like to do. The therapist and the client will then work together to try to understand anything that is making it difficult for the client to do these activities and to overcome these difficulties. The therapy aims to help the client to understand what they are experiencing and feeling, cope with it differently, and feel less worried when they do new things. The therapy sessions will be approximately weekly for up to 9 months. Some of the sessions will involve talking and others will involve going out and trying new things. Sessions are flexible and the timing and location of meetings will be decided between the client and therapist.

Why is the study called a 'randomised controlled trial'?

SRCBT is a relatively new therapy so we don't know whether or not it is helpful yet. To help us find out, we want to compare SRCBT together with the care you would usually get from your team with usual care alone. In order to do this, we will put people into two groups: one group will receive the SRCBT and the other group will not. The group that does not receive SRCBT is called the 'control' group and is very important as it allows comparisons to be made. This is why this type of trial is called 'controlled'. A computer will decide which of the two groups participants are in. The computer will make sure that each group has the same number of males and females and that the groups have an equal spread of ages and level of social difficulties. The computer will not have any other information about individuals so the decision about which group people go into will be random. This is what is meant by 'randomised'. The two groups will be the same size so participants have a 50/50 chance of receiving SRCBT in addition to usual care.

What will happen if I decide to take part?

If you decide to take part, you will meet with a PRODIGY research assistant, at a time and place to suit you, to complete an assessment. The research assistant will be independent from your usual care team. In the assessment, the research assistant will ask you some questions about your current difficulties and social situation and will ask you to complete some questionnaires. The assessment will take about one hour to complete. This can be done in a single session or spread over more than one session, whichever is more convenient and comfortable for you. You can invite a friend, relative or worker to be with you during the assessment if you like. If you would like, we will write a brief summary of the assessment in the form of a letter addressed to you. We can provide you with copies of the letter to share with your care team if you wish. After the assessment you will be put into either the group which will be offered SRCBT (the therapy group) or the group which will not (the control

group). You will be told which of the groups you have been put into by a member of the research team. We will also let your care team know which of the groups you are in. After nine months you will then meet with the research assistant again to repeat the research assessment, and once more after a further 6 months. This means you will be part of the project for up to 15 months.

If you are in the therapy group, in addition to your usual care you will be offered weekly or fortnightly meetings with a therapist for up to nine months. The therapy sessions will be at a time and place that is convenient for you. If you are in the control group you will still receive your usual care but without the additional SRCBT.

If you are at school or college, the research team may ask for your permission to speak with relevant staff members (for example, the school nurse, counsellor or special educational needs coordinator) to help make sure that you are being offered the best possible support. We would also ask school/college staff to let us know if they felt that your participation in the study was having a negative effect on your performance or attendance at school.

Some people from both the control and therapy groups may also be asked to take part in an interview with a trained research assistant. This interview will ask you about your experiences of taking part in the research study so far and will last for no more than an hour.

A small number of people may also be asked to take part in a more detailed interview at the end of the study. Even if you have taken part in the rest of the study, you are free to say no to this further interview. If you agree to take part in this interview, you will be asked about your psychological difficulties and history of using mental health services in more depth. The interview will be informal with questions designed to allow you to talk about what you feel is important. The interview can take place at a time and venue to suit you such as your home or GP surgery. The interview will last between 1 and 2 hours and will be audio recorded so that we have an accurate record of what you have said. Only members of the research team will listen to the recording. The recording will be stored securely for 10 years and then destroyed.

What are the possible risks of taking part?

If people feel pressurised into undertaking new activities they can sometimes find that certain psychological difficulties get worse or come back. However, the aim of SRCBT is to help people explore new activities they want to do while taking care to minimise the risk of any psychological difficulties.

What are the possible benefits of taking part?

We hope that the therapy will help those people who are offered it but we can't guarantee this. The information we find out from this research may help us to provide people with better help in the future. You will receive £20 at each research assessment as a thank you for giving up your time. If you complete the study, you will also be entered into a prize draw to win an iPod.

What happens when the research stops?

When the research project finishes, all participants will receive standard care from their usual team.

What happens if something goes wrong?

If you are harmed by taking part in a research project there are no special compensation arrangements. If you are harmed by someone's negligence you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any

aspect of the way you have been approached or treated during the course of the study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this project be kept confidential?

All information collected as part of this research including questionnaires, typed up notes of interviews and recording of interviews will be kept in a locked filing cabinet and secure IT systems on University or NHS sites. Data will be transferred between sites securely to ensure no-one outside the research team is able to access it. Any information from or about you will have your name, address and any other identifying features removed so that you cannot be recognised from it. This means that your anonymity will be preserved at all times during and after the study time period. All data will be destroyed 10 years after the study has been completed in line with NHS research policy.

If you are in the therapy group, we may audio record some of the sessions you have with your therapist with your permission. This is because we want to check that the therapy is being carried out in the way that we expect. All recordings will be stored securely and anyone listening to the tapes will sign a declaration of confidentiality.

If you consent, we will inform your GP and the team responsible for your care that you are taking part in the research project. The study team and individuals from authorities responsible for making sure the research is done properly may look at relevant sections of your medical records.

Where and how long will records be stored?

Data will be stored in locked cabinets and secure ICT systems on NHS or university premises. The data will be kept for 10 years after the completion of the study and then destroyed. Audio recordings of sessions will be stored electronically on secure ICT systems and destroyed 10 years after completion of the study.

What will happen to the results of the research?

The results of the study will be written up for publication in health professional journals and will be presented at conferences in the UK and abroad. When we report the results of the research we may quote some of your words, however your anonymity will be preserved at all times. If you would like to be kept informed of any publications resulting from the study, please let the research team know.

Who is organising and paying for the research?

The research is being paid for by the National Institute of Health Research (NIHR) Health Technology Assessment Programme and sponsored by Norfolk and Suffolk NHS Foundation Trust. The research is being carried out by researchers from Norfolk and Suffolk NHS Foundation Trust, Greater Manchester West Mental Health NHS Foundation Trust, University of East Anglia and The University of Manchester.

Who has approved the research?

Research projects like this one can't go ahead without being approved by an NHS Research Ethics Committee. The Ethics Committee checks that the risks associated with the study have been reduced to a minimum and balanced against potential benefits. They also check you have been given enough information to make an informed choice about whether or not to take part. This study has been considered and approved by the Norfolk Research Ethics Committee.

Where can I get more information?

For general information about taking part in research you can contact Norfolk and Suffolk NHS Foundation Trust's Research and Development Department using the following email address:

[contact details]

If you need further information about this specific project, please contact a member of the PRODIGY team. You can contact the team at any time using the following email address:

[contact details]

If you would prefer to contact the team by phone, the names and telephone numbers of some PRODIGY team members are given below. They can be reached during office hours, Monday to Friday.

[contact details]

Thank you for reading this!

Thank you for taking the time to read this information sheet. If you decide to take part in the project you will be given a copy of this sheet, together with a copy of your consent form, to keep.

B. Extension phase PRODIGY Randomised Controlled Trial Participant Information Sheet (Version 3.0 29/09/2015):

[insert site-specific logos]

PRODIGY: Prevention of long term social disability amongst young people with emerging psychological difficulties: a definitive randomised controlled trial of Social Recovery Cognitive Behavioural Therapy.

This project is funded by the National Institute for Health Research Health Technology Assessment Programme (project number 10/104/51).

Participant Information Sheet

You have been given this information sheet because you are being invited to take part in a research project. It is up to you to decide whether or not you want to take part. Before you decide, it is important that you know about the project. This information sheet will tell you about why the project is being done and what will happen if you decide to take part. Please take as much time as you need to read and understand this information: you can talk about it with other people if you want. If there is anything you don't understand you can speak to a member of the PRODIGY team. You will find the team's contact details at the end of this information sheet.

Why is the project being done?

Some young people who experience psychological difficulties sometimes find it hard to carry on living the life they want to live: they might have problems going to school or college, finding a job or taking part in social activities. "Social recovery" is a term used to describe when someone is living the life they want to despite having experienced psychological difficulties. We think that people might make a better social recovery if they work with a therapist using a technique called Social Recovery Cognitive Behavioural Therapy (SRCBT for short). This research project is being done to see whether working with a therapist in this way can help people to make a better social recovery.

Why have I been invited to take part?

We are inviting young people receiving support from youth services in East Anglia, Manchester and Sussex who are experiencing psychological difficulties and not spending much time doing structured activities to take part in the project. Structured activities include things like work, education, childcare, housework, sport and leisure activities. If you are interested in taking part in the project we will ask you some questions about how you are spending your time at the moment to help us decide whether this project is right for you.

Do I have to take part?

No, it is up to you to decide whether or not you want to take part. If you do decide to take part you will be given this information sheet to keep and will also be asked to sign a consent form. Even if you

decide to take part, you can change your mind at any time without having to give a reason. If you decide not to take part, or to stop taking part, this will not affect the standard of care you receive.

What is the therapy being tested?

The therapy being tested, Social Recovery Cognitive Behavioural Therapy (SRCBT), is a new talking therapy which aims to help individuals spend more time doing activities which are meaningful for them. During the therapy, the therapist works with a young person to identify activities they would like to do. The therapist and young person will then work together to try to understand anything that is making it difficult for them to do these activities and to overcome these difficulties. The therapy aims to help the young person to understand what they are experiencing and feeling, cope with it differently, and feel less worried when they do new things. The therapy sessions will be approximately weekly for up to 9 months. Some of the sessions will involve talking and others will involve going out and trying new things. Sessions usually last for about an hour. Sessions are flexible and the timing and location of meetings will be decided between the young person and therapist.

Why is the study called a 'randomised controlled trial'?

SRCBT is a relatively new therapy so we don't know whether or not it is helpful yet. To help us find out, we want to compare SRCBT, together with the care you would usually get from your team, with usual care alone. In order to do this, we will put people into two groups: one group will receive the SRCBT and the other group will not. The group that does not receive SRCBT is called the 'control' group and is very important as it allows comparisons to be made. This is why this type of trial is called 'controlled'. A computer will decide which of the two groups participants are in. The computer will make sure that each group has the same number of males and females and that the groups have an equal spread of ages and level of social difficulties. The computer will not have any other information about individuals so the decision about which group people go into will be random. This is what is meant by 'randomised'. The two groups will be the same size so participants have a 50/50 chance of receiving SRCBT in addition to usual care.

What will happen if I decide to take part?

If you decide to take part, you will meet with a PRODIGY research assistant, at a time and place to suit you, to complete an assessment. The research assistant will be independent from your usual care team (if you have one). In the assessment, the research assistant will ask you to complete four questionnaires with them about your current difficulties and social situation. The research assistant will then ask you to complete ten more questionnaires. The assessment will take about two hours to complete in total. This will be spread over two or more sessions, whichever is more convenient and comfortable for you. You can invite a friend, relative or worker to be with you during the assessment if you like. If you would like, we will write a brief summary of the assessment in the form of a letter addressed to you. We can provide you with copies of the letter to share with your care team if you wish. After the assessment you will be put into either the group which will be offered SRCBT (the therapy group) or the group which will not (the control group). You will be told which of the groups you have been put into by a member of the research team. If you have a current care team, we will also let them know which of the groups you are in.

You will be invited to meet with the research assistant again to repeat the assessment at three further time points: 9 months, 15 months and 24 months on from your first assessment. This means you will be part of the project for up to 2 years.

If you are in the therapy group, in addition to your usual care you will be offered weekly or fortnightly meetings with a therapist for up to nine months. The therapy sessions will be at a time and place that is convenient for you. If you are in the control group you will still receive your usual care but without the additional SRCBT.

If you are at school or college, the research team may ask for your permission to speak with relevant staff members (for example, the school nurse, counsellor or special educational needs coordinator) to help make sure that you are being offered the best possible support. We would also ask school/college staff to let us know if they felt that your participation in the study was having a negative effect on your performance or attendance at school, but we do not anticipate this to be the case.

What are the possible risks of taking part?

If people feel pressurised into undertaking new activities they can sometimes find that certain psychological difficulties get worse or come back. However, the aim of SRCBT is to help people explore new activities they want to do while taking care to minimise the risk of any psychological difficulties.

What are the possible benefits of taking part?

We hope that the therapy will help those people who are offered it but we can't guarantee this. The information we find out from this research may help us to provide people with better help in the future. You will receive £20 at each research assessment as a thank you for giving up your time.

What happens when the research stops?

When the research project finishes, all participants will receive standard care from their usual team.

What happens if something goes wrong?

If you are harmed by taking part in a research project there are no special compensation arrangements. If you are harmed by someone's negligence you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of the study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this project be kept confidential?

All information collected as part of this research including consent forms, questionnaires, typed up notes of interviews and recording of interviews will be kept in a locked filing cabinet and secure computer systems on University or NHS sites. Data will be transferred between sites securely to ensure no-one outside the research team is able to access it. Any information from or about you will have your name, address and any other identifying features removed so that you cannot be recognised from it. This means that your anonymity will be preserved at all times during and after the study time period. All data will be destroyed 10 years after the study has been completed in line with NHS research policy.

If you are in the therapy group, we may audio record some of the sessions you have with your therapist with your permission. This is because we want to check that the therapy is being carried out in the way that we expect. All recordings will be stored securely and anyone listening to the tapes will sign a declaration of confidentiality.

If you consent to participate in the study we will inform your GP and the team responsible for your care that you are taking part in the research project. If we believe that there is any risk to your safety

or the safety of anyone else, we will have to pass this information on to your GP and current care team.

With your permission, we may also share other information you give us during your assessments with your GP or current care team (or both) of the information your share with us during the assessments, for example, information about your mental health and social situation. The study team and individuals from authorities responsible for making sure the research is done properly may look at relevant sections of your medical records.

Where and how long will records be stored?

Data will be stored in locked cabinets and secure computer systems on NHS or university premises. The data will be kept for 10 years after the completion of the study and then destroyed. Audio recordings of sessions will be stored electronically on secure computer systems and destroyed 10 years after completion of the study.

What will happen to the results of the research?

The results of the study will be written up for publication in health professional journals and will be presented at conferences in the UK and abroad. When we report the results of the research we may quote some of your words, however your anonymity will be preserved at all times. If you would like to be kept informed of any publications resulting from the study, please let the research team know.

Who is organising and paying for the research?

The research is being paid for by the National Institute of Health Research (NIHR) Health Technology Assessment Programme and sponsored by Sussex Partnership NHS Foundation Trust. The research is being carried out by researchers from Sussex Partnership NHS Foundation Trust, Norfolk and Suffolk NHS Foundation Trust, Greater Manchester West Mental Health NHS Foundation Trust, University of Sussex, University of East Anglia and The University of Manchester.

Who has approved the research?

Research projects like this one can't go ahead without being approved by an NHS Research Ethics Committee. The Ethics Committee checks that the risks associated with the study have been reduced to a minimum and balanced against potential benefits. They also check you have been given enough information to make an informed choice about whether or not to take part. This study has been considered and approved by the Preston Research Ethics Committee (15/NW/0590).

Where can I get more information?

For general information about taking part in research you can contact your local NHS trusts' research and development department:

[contact details]

If you need further information about this specific project, please contact a member of the PRODIGY team. You can contact the team at any time using the following email address:
[contact details]

If you would prefer to contact the team by phone, the names and telephone numbers of some PRODIGY team members are given below. They can be reached during office hours, Monday to Friday.

[contact details]

If you would like to speak to someone independent of the PRODIGY team, for more information or if something goes wrong, you can speak to your local PALS (Patient Advice and Liaison Service).

[contact details]

Thank you for reading this!

Thank you for taking the time to read this information sheet. If you decide to take part in the project you will be given a copy of this sheet, together with a copy of your consent form, to keep.

NHS
National Institute for Health Research

C. PRODIGY Therapist Sub-study Participant Information Sheet (process evaluation sub-study three; Version 2.0 01/09/2017)

[Insert site-specific logo here]

Therapist Participant Information Sheet (Version 2.0 01/09/2017)

Study title: Social Recovery Therapy: Therapists' experience of coping and hope working with complex clients

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you.

Why is this research being done?

Therapists' experience of delivering therapy is an area which has so far been relatively overlooked in terms of scientific research. However it has the potential of offering important clues in terms of training, supervision and support of therapists using the intervention.

This study aims to look at therapists' experience of working with a particular group of clients who do not usually present in traditional mental health services.

What's involved in taking part in this research?

Participation in the study involves a single interview with the researcher. During this interview the researcher will focus on your experience of working with clients using Social Recovery Therapy, mainly in terms of coping and maintenance of hope. This is likely to last between 30 minutes to 1 hour. The interview will be carried out face-to-face in a convenient NHS or educational institution location or by telephone or Skype. The interview will be audio-recorded with your consent. The interviews will be transcribed verbatim by the researcher, and themes will be identified via qualitative process of research (interpretative phenomenological analysis). Participants will not be matched to their interview responses in anyway nor to themes. In this sense, the information provided by you (your data) will remain confidential.

Are there any advantages and disadvantages of participation in this research?

It is not expected that the interview will cause any distress to the participants. However, in the unlikely event that you experience distress during the interview, the researcher will stop the interview, discuss the issue with you and, if needed, direct you to sources of support.

There may be no immediate benefits to taking part in this research. However, it is hoped that you will have a positive experience in participating in an interview in which you can reflect on experience of delivering Social Recovery Therapy with different clients. We believe that the findings will be useful to future projects or services in which therapists deliver social recovery focused therapy to clients.

Is my participation voluntary?

Yes, it is up to you to decide whether or not you want to take part. If you do decide to take part you will be given this information sheet to keep and will also be asked to sign a consent form. Even if you decide to take part, you can change your mind at any time without having to give a reason. It will not be possible to remove your data from the study after April 2018, when the data will be analysed.

How would my participation be kept confidential?

Your participation will remain confidential. Names or other identifying materials will not be included in the transcript of your interviews, nor in any further publication of this work. Recording will be done digitally in audio and kept in a Sussex Partnership NHS Trust encrypted memory stick in a locked NHS cabinet and in a secure computer file, for 10 years after the close of the trial unless otherwise advised by the Sponsor.

Should you disclose any information that suggests any client or you yourself are at possible risk of any harm, this information would need to be passed on to your line manager to ensure that you and all clients are kept safe. The researcher would discuss the best way of passing on this information with you during or after the interview.

Who has reviewed this research?

The PRODIGY Trial has been approved by the Preston Research Ethics Committee (15/NW/0590). This amendment and its sub-protocol have been reviewed by the Health Research Authority.

Will this research be published?

The present research study will be presented as part of the Dissertation for the Doctorate in Clinical Psychology, University of Leicester. It is expected to be submitted before January 2019. The researcher plans to publish it as a research paper in a scientific journal.

Who is organising and paying for this research?

This research is being organised by Cat Sacadura, employed by Sussex Partnership NHS Foundation Trust, as part of an educational qualification at the University of Leicestershire. This research is being done as an amendment to the PRODIGY Trial, which is paid for by the National Institute of Health Research (NIHR) and sponsored by Sussex Partnership NHS Foundation Trust.

Who can be contacted about this research?

Cat Sacadura [contact details]

Academic Supervisor [contact details]

PRODIGY Chief Investigator [contact details]

PRODIGY Trial Manager [contact details]

Research and Development Department, Sussex Partnership NHS Foundation Trust

[contact details]

What if there is a problem or concern about this research study?

If you have a concern about any aspect of this study, you should ask to speak to the

Researchers, using the contact information above, who will do their best to answer your questions using the information above.

If you remain unhappy and wish to complain formally, please contact:

Lead Governance Officer, Sponsor [contact details]

In the event that something does go wrong and you are harmed during the research

and this is due to someone's negligence then you may have grounds for a legal action for compensation against Sussex Partnership NHS Foundation Trust but you may have to pay your legal costs.