ISRCTN47998710 https://doi.org/10.1186/ISRCTN47998710

# PRODIGY: Prevention of long-term social disability amongst young people with emerging psychological difficulties

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 28/11/2012 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 29/11/2012 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 27/01/2022 | Mental and Behavioural Disorders | |

## Plain English summary of protocol

Background and study aims
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. People might make a better social recovery if they work with a therapist using a technique called Social Recovery Cognitive Behavioural Therapy (SRCBT). SRCBT is a relatively new therapy so it is not yet known whether or not it is helpful. To help find this out, SRCBT needs to be compared with the care young people currently get. The aim of this study is to see whether working with a therapist in this way can help people to make a better social recovery.

Who can participate?
People aged 16 to 25 years who present to youth services in Sussex, East Anglia and Manchester with severe and complex mental health problems and who have associated social disability (defined as 30 hours a week or less spent participating in structured activity)

What does the study involve?
Participants are randomly allocated into two groups: one group receive the SRCBT and the other group do not. The programme lasts for 9 months with assessments at the beginning of the study and after 9, 15 and 24 months. The programme is also evaluated from the perspective of the participants.

What are the possible benefits and risks of participating?
It is hoped that the therapy will help those people who are offered it but this cannot be guaranteed. The information from this study may help to provide people with better help in the future. All participants are reimbursed for their time and are also entered into a prize draw on completion of the study. There are no known risks associated with participating in this study.

Where is the study run from?
1. Sussex Partnership NHS Foundation Trust (UK)

2. University of Sussex (UK)
3. University of East Anglia (UK)
4. University of Manchester (UK)
5. Norfolk and Suffolk NHS Foundation Trust (NSFT) (UK)
6. Greater Manchester West Mental Health NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2013 to February 2019

Who is funding the study?
National Institute of Health Research (NIHR) Health Technology Assessment (HTA) (UK)

Who is the main contact?
Clio Berry (Trial Manager)
c.berry@sussex.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Prof David Fowler

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# Additional identifiers

### Protocol serial number
HTA 10/104/501, 13341

# Study information

### Scientific Title
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

### Study objectives
Current hypothesis as of 31/07/2015:
The study is a definitive randomised controlled trial of cognitive behavioural therapy to prevent social disability amongst young people with emerging psychological difficulties.

The primary hypothesis is:
1. In young people who are socially disabled and have severe and complex non-psychotic mental health problems, SRCBT will be superior to ESC in improving social recovery (as measured by hours in constructive activity assessed on the Time Use Survey), over a 15-month follow-up period.

Secondary hypotheses are:
2. SRCBT will be superior to ESC in terms of cost-effectiveness.
3. SRCBT will be superior to ESC in effects on mental health symptoms (attenuated psychotic symptoms and emotional disturbance).

A successful internal pilot has confirmed the inclusion criteria, further informed the power calculation for the overall sample size, confirmed the feasibility of recruitment, clarified data management procedures, and evaluated the intervention from the subjective perspectives of participants.

The study will be a single blind, randomised controlled trial comparing standard care with standard care plus Social Recovery Cognitive Behavioural Therapy. Participants will be stratified by site, age, severity of social disability and symptomatic criteria, and randomised to treatment groups by a remote randomisation service applying a method of concealed allocation. The intervention will last for 9 months with assessments at baseline, 9 months, 15 months and 24 months. Participants will be recruited from early detection and youth services in Sussex, East Anglia and Manchester over a 15-month period.

Previous hypothesis:
The study is a pilot randomised controlled trial of cognitive behavioural therapy to prevent social disability amongst young people with emerging psychological difficulties. The aim of the study is to prepare for a large randomised controlled trial. The objectives are:

1. To provide an empirical basis to clarify inclusion criteria and gain information useful for power calculations in a future study
2. To estimate costs and effects in preparation for a health economic study
3. To assess recruitment rate, quality of data collection and follow up
4. To further clarify data management procedures building on experience in past trials
5. To refine the manual for intervention and undertake a highly detailed analysis of adherence to interventions to further clarify programmes of training, and define the level of experience of therapists required to undertake the intervention

The study will be a single blind, randomised controlled trial comparing standard care with standard care plus Social Recovery Cognitive Behavioural Therapy. Participants will be stratified by age, severity of social disability, and symptomatic criteria and randomised to treatment groups by a remote randomisation service applying a method of concealed allocation. The intervention will last for 9 months with assessments at baseline, 9 months and 15 months. A qualitative substudy will be embedded within the pilot trial to evaluate the intervention from the subjective perspectives of participants themselves. Participants will be recruited from early detection and youth services in East Anglia and Manchester over a 12 month period.

The primary hypothesis is that the intervention (Social Recovery Cognitive Behavioural Therapy) will lead to improvements in social recovery as measured by time spent in structured activity.

The secondary hypotheses are:
1. The intervention will reduce levels of attenuated psychotic symptoms and depression
2. The intervention will prove cost-effective

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Norfolk Research Ethics Committee, 07/09/2012, ref: 12/EE/0311
2. NRES Committee North West – Preston, 24/07/2015, ref: 15/NW/0590

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Mental Health / Psychosis

## Interventions
1. Social Recovery focused Cognitive Behavioural Therapy
2. Standard care

The intervention is Social Recovery oriented Cognitive Behavioural Therapy (SRCBT) and will be delivered by trained cognitive behavioural therapists and Clinical Psychologists. 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.

The previous sponsor for this trial (up to 31/07/2015) was:
Norfolk and Suffolk NHS Foundation Trust
Hellesdon Hospital
Drayton High Road
Norwich
NR6 5BE
United Kingdom

## Intervention Type
Behavioural

## Primary outcome(s)
Current primary outcome measures:
Time Use Survey (hours per week in structured activity) at 15 month follow-up

Previous primary outcome measures:
Time Use Survey (hours per week in structured activity) at baseline, post-intervention and 15 month follow-up

### Key secondary outcome(s))
Current secondary outcome measures:
Secondary outcomes include attenuated psychotic symptoms, anxiety, and depression (also assessed at baseline, 9 months, 15 months, and 24 months), in addition to time use at post-intervention (9 months) and 24 months, and intervention cost-effectiveness at 9 months, 15 months, and 24 months.

Previous secondary outcome measures:
Secondary outcomes include attenuated psychotic symptoms, anxiety, and depression. These are also assessed at baseline, 9 months, and 15 months.

### Completion date
01/02/2019

## Eligibility

### Key inclusion criteria
1. Young people (male & female) aged 16 to 25 with severe and complex mental health problems showing early signs of persistent social disability
2. Presence of impairment in social and occupational functioning indicated by patterns of structured and constructive economic activity of less than 30 hours per week and a history of social impairment problems lasting for a period of longer than 6 months
3. Presence of severe and complex mental health problems defined operationally as:
3.1. Having attenuated psychotic symptoms which meet criteria for an At Risk Mental State; or
3.2. Having less severe attenuated psychotic symptoms but having severe and complex mental health problems which score at least 50 on the Global Assessment of Function Scale (which indicates the presence of severe symptoms of at least two of depression, anxiety, substance misuse, behavioural or thinking problems or subthreshold psychosis to the degree to impair function).
4. Also having a history of at least moderate symptoms persisting for longer than 6 months

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Total final enrolment
270

### Key exclusion criteria
1. Age below 16 or above 25
2. Active positive psychotic symptoms or history of first episode psychosis
3. Severe learning disability (those with mild to moderate learning difficulties will not be excluded)
4. Organic neurological disorder
5. Unable to fully understand and answer standardised assessment questions or give informed consent due to insufficient English language proficiency

### Date of first enrolment
01/02/2013

### Date of final enrolment
01/01/2016

## Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
**Sussex Partnership NHS Foundation Trust**
Research & Development
Sussex Education Centre
Millview Hospital
Nevill Avenue
Hove
United Kingdom
BN3 7HZ

### Study participating centre
**Norfolk and Suffolk NHS Foundation Trust**
Hellesdon Hospital
Drayton High Road
Norwich
United Kingdom
NR6 5BE

### Study participating centre
**Greater Manchester West Mental Health NHS Foundation Trust**
Trust Headquarters
Bury New Road
Prestwich

Manchester
United Kingdom
M25 3BL

## Sponsor information

### Organisation
Sussex Partnership NHS Foundation Trust

### ROR
https://ror.org/05fmrjg27

## Funder(s)

### Funder type
Government

### Funder Name
Health Technology Assessment Programme

### Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

## Results and Publications

### Individual participant data (IPD) sharing plan
Not provided at time of registration

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Results article | results | 01/02/2015 | | Yes | No |
| Results article | results | 11/07/2017 | | Yes | No |
| Results article | Clinical and cost-effectiveness results | 26/01/2022 | 27/01/2022 | Yes | No |
| Funder report results | | 25/11/2021 | 30/11/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |