

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

Submission date 28/11/2012	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/01/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

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

Study website

<http://www.sussex.ac.uk/spriglab/research/current/prodigy>

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please contact c.berry@sussex.ac.uk to request a patient information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/02/2013

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

Age group

Adult

Sex

Both

Target number of participants

Planned Sample Size: 270; UK Sample Size: 270; 100 participants have already been recruited

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**

England

United Kingdom

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

Sponsor details

Research & Development
Sussex Education Centre
Millview Hospital
Nevill Avenue
Hove
England
United Kingdom
BN3 7HZ

Sponsor type

Hospital/treatment centre

Website

<http://www.sussexpartnership.nhs.uk/>

ROR

<https://ror.org/05fmrjg27>

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

To be confirmed at a later date

Intention to publish date

01/09/2018

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