# Combined individual and family cognitive behavioural therapy compared with treatment as usual

Submission date	Recruitment status  No longer recruiting	[X] Prospectively registered		
13/06/2016		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
15/06/2016		<ul><li>Results</li><li>Individual participant data</li></ul>		
Last Edited				
25/05/2021	Mental and Behavioural Disorders	<ul><li>Record updated in last year</li></ul>		

#### Plain English summary of protocol

Background and study aims

Psychosis is a serious mental disorder in which thought and emotions are impaired, causing a person to lose touch with reality. The onset of psychosis is a major challenge for the patient and everyone involved in his or her care. It is unusual for psychosis to come on suddenly, and the NHS is keen to look at treatments to help stop the progression of psychosis for people at risk of developing it. Prevention is preferable to treatment for fully developed psychosis, because it is usually more acceptable and is generally associated with fewer side effects. It can also be more cost effective to provide prevention-based treatments. It is now possible to identify people who are at a high risk of developing psychosis. Early intervention teams around the country are working to help prevent the full onset of psychosis, as otherwise about one third will develop a full psychosis within three years. This study is going to look at treatments that aim to help reduce the number of people who develop psychosis. The aim of this study is to find out if adding family therapy to individual treatment is a helpful preventative treatment for young people at risk of developing psychosis.

#### Who can participate?

Young people aged 16-35 who are living with at least one member of their family and are at risk of developing psychosis.

#### What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group are offered combined individual and family Cognitive Behavioural Therapy plus their usual treatment. This involves a maximum of 25 individual cognitive behavioural therapy sessions (usually one per week) lasting up to an hour over a 6 month period, as well as 4-6 sessions of therapy with key family members or family support members. Therapy sessions will focus on whatever is of most concern to the participant at the time. Those in the second group continue to receive their treatment as usual, with no additional therapy from the research team. Participants in both groups will meet with a researcher for an initial assessment (which involves discussing current mental health difficulties and completing some questionnaires), and complete follow up assessments after 6 months and 12 months to repeat the initial questionnaires. Family members

will also be asked to complete some questionnaires at the initial assessment, 6 month follow up and 12 month follow up assessment. Finally, a selection of those who take part are interviewed about their experiences in the study to help the research team decide whether a larger study should take place to explore the research further.

What are the possible benefits and risks of participating?

It is hoped that the combined individual and family therapy will be beneficial to those who are offered it but this cannot be guaranteed, and not everyone will be offered the therapy as part of the trial. This means there may be no direct benefits for those taking part in the study although many people find being involved in research to be a positive experience. There are no risks involved with taking part in the study. It is possible that some people may find talking about their mental health and their experiences distressing, however plenty of opportunities will be provided to discuss any concerns and participants can choose not to continue with the study if they wish.

Where is the study run from?

- 1. Greater Manchester West Mental Health NHS Foundation Trust (UK)
- 2. Bolton Early Intervention in Psychosis Team (UK)
- 3. Salford Early Intervention in Psychosis Team (UK)
- 4. Trafford Early Intervention in Psychosis Team (UK)

When is the study starting and how long is it expected to run for? March 2016 to April 2019

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact?

- 1. Dr Heather Law (public)
- 2. Professor Paul French (scientific)

### **Contact information**

#### Type(s)

Public

#### Contact name

Dr Heather Law

#### **ORCID ID**

https://orcid.org/0000-0002-1889-9179

#### Contact details

Greater Manchester West Mental Health NHS Foundation Trust Psychosis Research Unit-Rico House Harrop House Bury New Road Prestwich Manchester United Kingdom M25 3BL

#### Type(s)

Scientific

#### Contact name

Prof Paul French

#### Contact details

Greater Manchester West Mental Health NHS Foundation Trust Psychosis Research Unit-Rico House Harrop House Bury New Road Prestwich Manchester United Kingdom M33 7FT

# Additional identifiers

#### Protocol serial number

30981

# Study information

#### Scientific Title

Combined individual and family therapy in comparison to treatment as usual for people at risk of psychosis: A feasibility study

#### Acronym

**IF-CBT Trial** 

#### **Study objectives**

The aim of this study is to investigate whether a combined individual and family intervention is an acceptable, feasible and potentially effective treatment option for people with an At Risk Mental State (ARMS) for psychosis compared to standard treatment.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

North West - Greater Manchester East Research Ethics Committee, 26/05/2016, ref: 16/NW/0278

#### Study design

Randomised; Interventional; Design type: Treatment, Psychological & Behavioural

#### Primary study design

Interventional

#### Study type(s)

**Treatment** 

#### Health condition(s) or problem(s) studied

Specialty: Mental Health, Primary sub-specialty: Psychosis; UKCRC code/ Disease: Mental Health/ Organic, including symptomatic, mental disorders

#### Interventions

Participants are randomised to one of two groups using a secure telephone randomisation system in a 1:1 ratio.

Combined individual and family therapy: Participants will be offered a combined individual and family Cognitive Behavioural Therapy plus their usual treatment. A maximum of 25 individual therapy sessions will be available (usually one per week) lasting up to an hour, over a 6 month period. Therapy sessions will focus on whatever is of most concern to the participant at the time. Alongside this, 4-6 sessions of Cognitive Behavioural Therapy with key family members or family support members will be available. These sessions will focus on making sense of experiences, communication styles, problem solving and goal setting.

Usual treatment alone: Participants in this study arm will not be offered any additional treatment from the study. They will continue with routine care or 'treatment as usual' from their care team or GP.

All participants will meet with a researcher for a follow up assessment at 6 months and 12 months after randomisation.

#### Intervention Type

Other

#### Primary outcome(s)

Transition to psychosis as defined by the Comprehensive Assessment of At Risk Mental States at baseline, 6 and 12 months.

#### Key secondary outcome(s))

- 1. Time use is measured using the time use survey at baseline, 6 and 12 months
- 2. Depression is measured using the Beck Depression Inventory at baseline, 6 and 12 months
- 3. Social anxiety is measured using the Social Interaction Anxiety Scale at baseline, 6 and 12 months
- 4. Use of formal and informal health and social care is measure using the adapted EPQ at baseline, 6 and 12 months
- 5. Health status is measured using the EQ-5D at baseline, 6 and 12 months

#### Completion date

01/04/2019

# Eligibility

#### Key inclusion criteria

- 1. Aged 16-35
- 2. Screen positive on the Comprehensive Assessment of At Risk Mental States (CAARMS) for an At Risk Mental State
- 3. Be living with at least one member of their family
- 4. Help seeking

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### Key exclusion criteria

- 1. Current or previous receipt of anti-psychotic drugs
- 2. Moderate to severe learning disability
- 3. Organic impairment
- 4. Insufficient fluency in English
- 5. Significant risk to self or others

#### Date of first enrolment

27/06/2016

#### Date of final enrolment

27/01/2018

#### Locations

#### Countries of recruitment

United Kingdom

England

#### Study participating centre

#### Greater Manchester West Mental Health NHS Foundation Trust

Psychosis Research Unit Rico House Harrop House **Bury New Road** Prestwich

Manchester

United Kingdom

M33 7FT

Study participating centre **Bolton Early Intervention in Psychosis Team** 

**Bentley House** 

Viking Works Weston Street Bolton United Kingdom BL3 2RX

#### Study participating centre Salford Early Intervention in Psychosis Team

Broadwalk Centre 51 Belvedere Road Salford United Kingdom M6 5EJ

# Study participating centre Trafford Early Intervention in Psychosis Team

Crossgate House Cross Street Sale United Kingdom M33 7FT

# Sponsor information

#### Organisation

Greater Manchester West Mental Health NHS Foundation Trust

# Funder(s)

#### Funder type

Government

#### **Funder Name**

National Institute for Health Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### **Funding Body Type**

#### Government organisation

#### Funding Body Subtype

National government

#### Location

United Kingdom

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not expected to be made available

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		01/02/2021	25/05/2021	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes