

The EXTEND trial: evaluating the effectiveness of extended early intervention for psychosis treatment

Submission date 28/09/2020	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2020	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/01/2021	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Psychosis involves seeing or hearing things that other people cannot see or hear (hallucinations) and believing things that are not actually true (delusions). Early Intervention in Psychosis (EIP) services are specialist community mental health teams that treat people who are/or have recently experienced a first episode of psychosis (FEP). Teams provide a range of treatments including medication, psychotherapy, psychoeducation, and occupational, educational and employment support, augmented by regular contact with the service user. Treatment is offered for three years after which service users are either discharged to primary care or transferred to a standard adult community mental health team (CMHT). EIP services are clinically effective, improving symptoms and reducing psychiatric hospitalisations, and are likely to be cost-saving. Once EIP treatment ends, improvements are not sustained, bringing uncertainty about the optimal duration to offer EIP to ensure good long-term outcomes. Three previous trials of extended EIP have reported conflicting results. There is a clear and urgent need to establish whether continued EIP treatment is more clinically and cost-effective than standard EIP, and whether it can improve the long-term outcomes of those with FEP. The aim of this study is to assess the clinical and cost-effectiveness of extending treatment in EIP services up to 5 years.

Who can participate?

Patients with psychosis who are currently on the caseload of an EIP team and who have received 2.5 years of treatment

What does the study involve?

Participants will be randomly assigned to receive either a two-year extended EIP treatment or treatment as usual (TAU). For those receiving the additional 2 years of EIP, there will be a continued emphasis on individualised care, whereby clinicians flexibly offer National Institute for Clinical Excellence approved treatments to maximise recovery. EIP flexible treatments include intensive care coordination, specialist psychological interventions, including cognitive behavioural therapy for psychosis (CBTp) and family therapy, specialist pharmacological intervention, support with employment/education and social recovery, physical health and wellbeing monitoring, families/carers support, and crisis and relapse planning. Those who are

allocated to TAU will either be transferred to a standard adult community mental health team or be discharged to primary care.

Everyone who takes part will be asked to meet with a research assessor at the beginning of the study, after 30 months and after 42 months. During these meetings, they will be asked to complete questionnaires about their receipt of services, their health, and their quality of life.

What are the possible benefits and risks of participating?

The researchers do not anticipate any risk of taking part in the study. As with all research of this nature there is no guarantee that people will experience direct benefits as a result of participating. However, there may be future benefits to early psychosis care as this study is likely to influence how this care is given in the future.

Where is the study run from?

Pennine Care NHS Foundation Trust (UK)

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

January 2020 to November 2026

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Prof. Paul French

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

CPMS 45301, NIHR129501

Study information

Scientific Title

Extended treatment in early intervention in psychosis services: randomized controlled trial, mixed methods sub-study and health economic analysis

Acronym

EXTEND

Study objectives

What is the clinical and cost-effectiveness of extending treatment in early intervention in psychosis (EIP) services up to 5 years on patient recovery?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 29/04/2020, North East - Newcastle & North Tyneside 2 Research Ethics Committee (NHS BT Blood Donor Centre, Holland Drive, Newcastle upon Tyne, Tyne and Wear, NE2 4NQ, UK; +44 (0)207 1048091; newcastlenorthtyneside2.rec@hra.nhs.uk), REC ref: 20/NE/0112

Study design

Multicenter parallel-group randomized controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Individuals with psychosis who are have recieved 2.5 years of treatment by Early Intervention in Psychosis (EIP) services

Interventions

Participants will be randomized (1:1) to extended early intervention or treatment as usual (discharged to either primary care or a community mental health team). Participants will be between 30 and 32 months into their standard EIP treatment (allowing sufficient time for the control group to experience a well-managed discharge). Randomization will be stratified by site, gender and age using permuted blocks of random size. The research assistant performing the randomization will access a web-based randomisation system provided by the clinical trials research unit.

Participants allocated to extended EIP will complete their standard 3 year EIP treatment, after which they will receive a further 2 years of extended EIP treatment. Extended EIP treatment follows the same principles as standard EIP, providing assertive community contact, augmented by a flexible treatment plan which can include cognitive behavioural therapy for psychosis

(CBTp) and family therapy, specialist pharmacological intervention, support with employment /education and social recovery, physical health and wellbeing monitoring, families/carers support, and crisis and relapse planning.

Participants allocated to treatment as usual will complete their standard 3 year EIP treatment, after which they will either be discharged to their primary care provider or transferred to an adult community mental health team as is standard clinical practice.

All participants will be followed-up for a total of 42 months from randomization.

Intervention Type

Mixed

Primary outcome(s)

Relapse rate, defined as admission to a psychiatric hospital or acceptance to the caseload of a service designated as a hospital alternative, including crisis resolution team, crisis house, home treatment team, or other acute mental health service. Collected using medical records at 30-month and 42-month follow-up.

Key secondary outcome(s)

1. Recovery-focused quality of life measured using Recovering Quality of Life (REQoL), collected via research interview at baseline and 42-month follow-up
2. Quality-adjusted life-years (QALYs) calculated using EQ-5D, collected via research interview at baseline and 42-month follow-up
3. Subjective recovery from psychosis measured using questionnaire about the Process of Recovery (QPR), collected via research interview at baseline and 42-month follow-up
4. Service utilisation, income, accommodation and other cost-related variables measured using Client Service Receipt Inventory (CSRI), collected via research interview at baseline and 42-month follow-up
5. Number Not in Education, Employment or Training (NEET) status, collected via research interview at baseline and 42-month follow-up
6. Time to relapse, defined as per the primary outcome measure, collected using medical records at 30-month and 42-month follow-up
7. Number of days in psychiatric hospital, collected using medical records at baseline, 30-month and 42-month follow-up
8. Disengagement from services, collected using medical records at 30-month and 42-month follow-up
9. All-cause mortality, collected using national mortality records at 30-month and 42-month follow-up

Completion date

30/11/2026

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

Individuals who have completed 2.5 years of EIP treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Key exclusion criteria

1. People who are unable to receive community treatment, because they are admitted to forensic inpatient units or have been a hospital inpatient for a year or more at time of recruitment
2. Inability to provide informed consent

Date of first enrolment

01/06/2021

Date of final enrolment

30/11/2022

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Pennine Care NHS Foundation Trust

225 Old Street

Ashton-under-Lyne

United Kingdom

OL6 7SR

Sponsor information**Organisation**

Pennine Care NHS Foundation Trust

ROR

<https://ror.org/03t59pc95>

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

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No