ISRCTN13235578 https://doi.org/10.1186/ISRCTN13235578

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

Submission date
28/09/2020

Recruitment status
Stopped

Registration date
29/09/2020

Overall study status
Stopped

Last Edited
11/01/2021

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 recieved 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
P.French@mmu.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Paul French

Contact details
Pennine Care NHS Foundation Trust
225 Old Street
Ashton-under-Lyne
United Kingdom
OL6 7SR
+44 (0)161 716 3000
P.French@mmu.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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.

Partcipants 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 measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2020

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

Age group
Mixed

Sex
Both

Target number of participants
1092

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
England

United Kingdom

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

Sponsor details
225 Old Street
Ashton-under-Lyne
England
United Kingdom
OL6 7SR
+44 (0)161 716 3080
reagan.blyth@nhs.net

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03t59pc95

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

The protocol will be published in a peer-reviewed scientific journal. Results of the study will be published in a high-impact peer-reviewed scientific journal at the end of the trial and via a final report from the National Institute for Health Research (the funder). The researchers will provide specific reports on trial findings for healthcare policymakers. With the support of the Trial advisory group, they will ensure that key research evidence is made available to the Department of Health, NHS Trusts, CCGs, Royal College of Psychiatrists, and other stakeholders.

Intention to publish date

01/07/2027

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