

Early intervention dental trial

Submission date 04/10/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/11/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 03/10/2018	Condition category Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and aims

People with mental illness tend to have more dental problems than people without. Oral health problems are not well recognised by mental health professionals and when treatment is accessed, people with mental illnesses generally experience barriers to treatment.

The aim of this study is to see whether a simple checklist can improve the oral health of people with serious mental illness.

Who can participate?

Anyone aged over 18 years old who is cared for by an Early intervention in Psychosis team in Nottinghamshire, Derbyshire or Lincolnshire can take part.

What does the study involve?

Early Intervention in Psychosis teams will be randomly allocated to receive either dental awareness training for care coordinators plus using a dental health checklist with standard care or to standard care alone. All service users within the same team will receive the same intervention.

What are the possible benefits and risks of participating?

If service users agree to complete the checklist, they will gain more information about how to look after their teeth. We do not think there will be any negative side effects from the checklist. Only people who are cared for by one of the teams on the day during which we allocate participants to one of the treatments will be able to take part, but if the checklist is found to improve the oral health of the people who completed it, every person cared for by the teams will be given the opportunity to use the checklist.

Where is the study run from?

Within psychosis teams in Nottinghamshire, Derbyshire and Lincolnshire (UK). and will be delivered as part of standard care.

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

The trial started in October 2011 and will run for one year.

Who is funding the study?

The study is funded by National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care (CLAHRC).

Who is the main contact?

Ms Hannah Jones (Research Assistant)

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

10105

Study information

Scientific Title

The three Shires early intervention dental trial

Study objectives

To examine whether dental awareness training plus an oral health checklist will improve the oral health of the "Early Intervention in Psychosis" population in the East Midlands, United Kingdom

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee East Midlands, 1 Nottingham 11/08/2011, ref: 11/EM/0205

Study design

Multicentre cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Oral health

Interventions

Team dental awareness training plus an oral health checklist plus standard care versus standard care alone

Intervention Type

Behavioural

Primary outcome measure

Visit to dentist within one year of exposure to checklist

Secondary outcome measures

1. Registration with a dentist
2. Frequency of tooth brushing
3. Reason for dental visit (routine vs for problem)
4. Quality of life
5. Economic data
6. Leaving the study

Overall study start date

01/10/2011

Completion date

30/09/2013

Eligibility

Key inclusion criteria

1. Any willing early intervention in psychosis team in Nottinghamshire, Derbyshire or Lincolnshire
2. Service users cared for by the care coordinators within these teams aged over 18 years old at randomisation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

600-800

Key exclusion criteria

1. Any early intervention in psychosis team that does not wish to take part
2. Any individual care coordinator or service user within a team that does not wish to take part
3. Any service user aged less than 18 years old at randomisation

Date of first enrolment

01/10/2011

Date of final enrolment

30/09/2013

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Cochrane Schizophrenia Group

Nottingham

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NG7 2TU

Sponsor information

Organisation

University of Nottingham (UK)

Sponsor details

Research Innovation Services
Kings Meadow Campus
Lenton Lane
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Sponsor type

University/education

Website

<http://www.nottingham.ac.uk/>

ROR

<https://ror.org/01ee9ar58>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Collaboration for Leadership in Applied Health Research and Care (CLAHRC)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	29/05/2013		Yes	No