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LEGS Cluster Randomized Trial: Liaison with Education and General Practices to Detect and Refine Referrals of People with At-Risk-Mental-States (ARMS)

Submission date
28/05/2010

Recruitment status
No longer recruiting

Registration date
28/05/2010

Overall study status
Completed

Last Edited
25/08/2015

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
7036

Study information

Scientific Title
LEGS Cluster Randomized Trial: Liaison with Education and General Practices to Detect and Refine Referrals of People with At-Risk-Mental-States (ARMS)

Acronym
LEGS Trial: Liaison with PCPs and HEIs to Refine Referrals of ARMS

Study objectives
In order to do really early intervention in psychosis we need to find people early, those with At-Risk-Mental-States (ARMS) of developing such illness. International efforts to decrease the stigma of psychosis and solicit self- and other referrals have exploited print and television media for public information campaigns, as well as educating members of relevant occupational groups. The Norwegian 'TIPS' projects and the Australian ORYGEN/PACE are exemplars regarding ARMS detection; neither of them was a randomised design for ARMS, nor did they use propensity or other appropriate methods to compare areas with and without the intervention. TIPS has no economic evaluation but is certainly very expensive. There was evidence that existing cases of psychosis (with long duration of untreated psychosis) were found, but it was less clear what worked in terms of finding ARMS. Influential work in Denmark and Australia has also taken this approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 09/H0304/46)

Study design
Multicentre randomised interventional diagnosis, prevention and treatment trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Mental Health Research Network, Primary Care Research Network for England; Subtopic: Schizophrenia, Not Assigned, Psychosis, Service Delivery; Disease: Schizophrenia, Psychosis, All Diseases

Interventions
We are going to test whether a simple 'postal' campaign coordinated from an office is more effective and cost-effective than a more elaborate system of personal liaison by a health professional with the Primary Care Practices [PCPs] and the Higher Education Institutions [HEIs], as has been deployed in the international work cited above: a low versus high intensity strategy.

Study entry: single randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Yield in terms of ARMS referrals

Secondary outcome measures
Comparison of referral rates

Overall study start date
22/12/2009

Completion date
06/05/2013

Eligibility

Key inclusion criteria
Liaison phase:
1. PCPs and HEIs in Cambridgeshire and Peterborough areas
2. Signed agreement form from PCPs Partners and HEIs

Follow-up phase (at-risk-mental-states' data collection):
3. Patients confirmed as at-risk-mental-states for psychosis after being previously identified by PCPs and/or HEIs
4. Informed consent signed for data collection

All:
5. Male and female, aged 16 years or older

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
Planned sample size: 90; UK sample size: 90

Key exclusion criteria
Lack of mental capacity to provide informed consent

Date of first enrolment
22/12/2009

Date of final enrolment
06/05/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridgeshire and Peterborough NHS Foundation Trust (UK)

Sponsor details
Cambridge Road
Fulbourn
Cambridge
England
United Kingdom
CB21 5EF

Sponsor type
Hospital/treatment centre

Website
http://www.cpft.nhs.uk/

ROR
https://ror.org/040ch0e11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK)

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

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	17/07/2013		Yes	No
Results article	results	01/11/2015		Yes	No