

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	☐ Prospectively registered
Registration date 28/05/2010	Overall study status Completed	☒ Protocol
Last Edited 25/08/2015	Condition category Mental and Behavioural Disorders	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Peter Jones

Contact details

Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

-
pbj21@cam.ac.uk

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

Yield in terms of ARMS referrals

Key secondary outcome(s)

Comparison of referral rates

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Addenbrooke's Hospital

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridgeshire and Peterborough NHS Foundation Trust (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

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