# 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	Recruitment status  No longer recruiting	Prospectively registered		
28/05/2010		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
28/05/2010	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
25/08/2015	Mental and Behavioural Disorders			

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

**Prof Peter Jones** 

#### Contact details

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## 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
<u>Protocol article</u>	protocol	17/07/2013		Yes	No