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The National Knowledge Service Tuberculosis Pilot Evaluation Study

Submission date	Recruitment status	[_] Prospectively registered
18/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/02/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.hpa.org.uk/tbknowledge/default.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of information resources: a randomised control study and qualitative review

Acronym
The NKS- TBP Evaluation Study

Study objectives
Tuberculosis is a serious, but treatable infectious disease. About 8,000 new cases of TB are currently reported each year in the United Kingdom (Annual Surveillance report 2006). In 2004 the national action plan "Stopping Tuberculosis in England" set out a strategy for the "reduction and ultimately elimination of TB in the UK". The immediate targets in the action plan are to:
1. Reduce risk of TB
2. Provide high quality treatment for all with TB and
3. Maintain low levels of drug resistance
The first recommendation on how to accomplish these tasks is by "increasing awareness" among healthcare professionals, high risk groups and people who work with them and patients and member of the public. Educational interventions has clearly demonstrated to help General Practitioner's detect tuberculosis in primary care.

The aim of this project is to mobilise current evidence-based guidance and expert opinion to create knowledge and inform decision-making by professionals, carers and the public with regards the recognition and management of tuberculosis (TB).

The National Knowledge Service Tuberculosis Pilot (NKSTBP) was set up to provide information that would be directly relevant to people who need to be aware of, and take actions about, the treatment, prevention and management of TB. The target audience are patients, members of the public and healthcare professionals, others with a duty of care.

Information resources have been/are being developed to raise awareness on TB among target groups as identified by members of the NKSTBP programme board. As the rate of tuberculosis is higher among certain vulnerable groups the NKSTBP considered that carers who are working closely with these groups should be made targeted in the effort to raise awareness and knowledge of TB in the first instance. This should provide key staff with some guidance on how they can help and support their clients.

This study aims to evaluate a variety of information resources for specific target groups using a multi method approach. The evaluation will determine whether the information has contributed to an in increase in knowledge about TB. The methods to be used for the evaluation include:
1. A qualitative study to explore the opinion of targeted users regarding the benefits of and how best to present these leaflets
2. An observational study using a before and after approach to assess the gain in knowledge
3. A randomised controlled trial to determine whether the leaflets have contributed to a gain in short term knowledge of TB

It is the randomised controlled trial that is the subject of this protocol.

Ethics approval required
Old ethics approval format

Ethics approval(s)
A formal enquiry was sent to the Camden & Islington Community Local Research Ethics Committee based on the first batch of resources (Homeless sector) produced for this project, which we will be evaluating using the same study design. Application was submitted on the 11th of June 2007 and a reply was received on the 11th of July confirming that this study is an evaluation of a health service and therefore does not require full ethical review.

Study design
Multi-centre randomised controlled trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Tuberculosis (TB)

Interventions
To detect a 40% increase in knowledge between the two arms with 80% power 5% error, a sample size of 180 participants are required. Randomisation will be undertaken using random numbers generated on the Statistical software Stata by the study team at the Centre for Infections in Colindale. The allocation is then communicated to the head of the relevant organisation for each person to be sent either an intervention or control information resource. The group conducting the study will be blinded to the intervention received by each participant.

The intervention being evaluated is an information leaflet about various aspects of tuberculosis. Resources provided have information on the following:
1. Recognizing the key symptoms, diagnosis and treatment available
2. Client advocacy
3. How to support treatment
4. Referral pathway
5. Risks and precautions for staff
6. Website addresses were further information can be obtained

Participants allocated to the control group will receive a resource which is not on TB, e.g., "mental health and substance mis-use."

The gain in knowledge among participants will be compared using "intention to treat analysis". The ratio of proportional gain in knowledge will be adjusted for previous knowledge and experience of tuberculosis. Knowledge gain will be assessed through before and after questionnaires.

Total duration of intervention: 4 months (from 15th January 2008 to 15th May 2008)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Gain in knowledge as measured by the difference in score obtained after the intervention compared to the level before the intervention (questionnaires).

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/01/2008

Completion date
15/05/2008

Eligibility

Key inclusion criteria
The main inclusion criterion for qualitative whole study is that individuals must fall within the targeted groups. These groups include:
1. Drug and alcohol mis-users and staff working with them
2. Patient information sheet (pregnancy leaflet)
3. Clinicians (managing pregnant women exposed to TB)
4. Homeless sector staff/managers (TB and homelessness)
5. Staff of the Asylum Seekers
6. Staff taking care of children with TB
7. Prison staff
8. Prisoners (cartoon leaflets on TB)

For the randomised controlled trial component of the study, staff working with drug and alcohol mis-users and asylum seekers will be targeted. Individuals will be invited to participate through emails sent via their organisations mailing list. A sampling frame is available which consists of a list of all individuals employed by each organisation.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
180

Key exclusion criteria
Individuals who either do not consent or those who are not in the relevant target group

Date of first enrolment
15/01/2008

Date of final enrolment
15/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Health Protection Agency
London
United Kingdom
NW9 5EQ

Sponsor information

Organisation
Health Protection Agency (UK)

Sponsor details
61 Colindale Avenue
Colindale
London
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NW9 5EQ

Sponsor type
Government

Website

http://www.hpa.org.uk/

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health - The Health Protection Agency (UK)

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?
Results article	results	01/12/2008		Yes	No