

Promoting testicular self-examination and awareness amongst young men with learning disability

Submission date 24/06/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/10/2019	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Testicular cancer is the most common type of cancer affecting males between 15 and 34 years of age. Evidence suggests that men with intellectual disabilities (ID) are at increased risk of testicular cancer and may present late in the progression of the disease. The aim is to study the effect of two different educational programs in young men with ID.

Who can participate?

Males aged 16 or over, registered with a GP, known to learning disability services or on the learning disability register or known to have Down syndrome and the ability to consent.

What does the study involve?

Participants will be randomly assigned to either a teaching group or a leaflet group. The teaching sessions will be carried out with small groups with a maximum of six members in each. The teaching will be conducted by a Community Learning Disability Nurse Manager and a research assistant with learning disabilities. The teaching will be carried out in two 30-minute sessions. Participants in the leaflet group will be given a seven-page pictorial leaflet and encouraged to take it away and discuss with family, friends or carers if they wish. The effects of the interventions were assessed in terms of knowledge and skills, attitudes and anxiety one week after the interventions and again after 6 months.

What are the possible benefits and risks of participating?

This study teaches young men with ID how to spot the early signs of testicular cancer. Testicular cancer is almost always curable if found early. When young men with ID receive information in an accessible form they can feel more confident about having influence over their health and seeking help, leading to reduced anxiety levels. There are no foreseeable risks to participants.

Where is the study run from?

In London at various colleges, day centres, voluntary organisations and youth clubs

When is the study starting and how long is it expected to run for?
The study took place between 2002 and 2003

Who is funding the study?
Department of Health - Primary Care Studies Programme

Who is the main contact?
Baroness Hollins
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Promoting testicular self-examination and awareness amongst young men with learning disability: a randomised controlled trial

Study objectives
Null Hypothesis: Men who take part in a teaching programme will not illustrate a greater knowledge of testicular cancer, symptoms and signs or a greater skill with regard to self-examination than the control group who receive a suitably designed leaflet on the subject within (a) one week of intervention and (b) six months after the intervention.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Wandsworth LREC, 25/10/2011, ref: 01.78.23
2. Kingston and Richmond LREC, November 2001
3. Merton and Sutton LREC, November 2001

Study design

Multi-centre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Diagnostic

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

Testicular cancer awareness

Interventions

1. Teaching programme (intervention group)
2. Educative leaflet (control)

The intervention group received two 30-minute education sessions and the control group received a 7-page pictorial leaflet. The follow-up was at 1 week and again at 6 months. The duration of the intervention was 6 months

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

1. State / Trait Anxiety Inventory
2. Wells Health Anxiety
3. Health Locus of Control, confidence and self-efficacy with regard to testicular self-exam and seeking help

All measures adopted existing inventories so as to be accessible to learning disability group. Used linear analogue scales. Measured at baseline, one week and six months post intervention.

Secondary outcome measures

Assessment of health anxiety

Overall study start date

01/12/2001

Completion date

30/03/2003

Eligibility

Key inclusion criteria

1. Males aged 16 or over
2. Registered with a general practitioner (GP)
3. Known to learning disability services or on the learning disability register or known to have Down Syndrome
4. Have capacity to consent

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

192 (96 per arm of study)

Key exclusion criteria

Lack of capacity to consent

Date of first enrolment

01/12/2001

Date of final enrolment

30/03/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
St George's University of London
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's University of London (UK)

Sponsor details
Cranmer Terrace
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SW17 0RE

Sponsor type
University/education

Website
<http://www.sgul.ac.uk/>

ROR
<https://ror.org/040f08y74>

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK) - Primary Care Studies Programme

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	01/06/2018	24/10/2019	Yes	No