ISRCTN67971984 https://doi.org/10.1186/ISRCTN67971984

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

Submission date
24/06/2011

Recruitment status
No longer recruiting

Registration date
25/08/2011

Overall study status
Completed

Last Edited
24/10/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
shollins@sgul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Sheila Hollins

Contact details
St George's University of London
Division of PHSE
Cranmer Terrace
London
United Kingdom
SW17 0RE
-
shollins@sgul.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)
Diagnostic

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(s)
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.

Key secondary outcome(s))
Assessment of health anxiety

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

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
United Kingdom

England

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

Sponsor information

Organisation
St George's University of London (UK)

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Government

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

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	01/06/2018	24/10/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes