Patient involvement in prostate cancer treatment decisions

Submission date	Recruitment status	Prospectively registered
12/09/2005	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2005	Completed	[X] Results
Last Edited	Condition category	Individual participant data
28/11/2007	Cancer	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr PFM Stalmeier

Contact details

Radboud University Nijmegen MC MTA 138 PO Box 9101 Nijmegen Netherlands 6500 HB +31 (0)24 3610592 p.stalmeier@mta.umcn.nl

Additional identifiers

Protocol serial number

Dutch Cancer Society 2001-2379; NTR63

Study information

Scientific Title

Study objectives

How many and which patients want to choose their own radiation dose?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics committee CWOM number 0012-0284. Ethics approval date 16 March 2001.

Study design

Non randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Control group is usual care (150 patients). Intervention group is usual care plus decision aid (150 patients).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Primary outcome measure is choice acceptance. At the end of the interview, the patient is asked whether he wants to choose one of the two treatment options, or whether he wants to leave the decision to the physician. The response to this question is choice acceptance. Choice acceptance is confirmed by telephone 2 days later. This measure is obtained about 10 days after the first consultation.

Key secondary outcome(s))

- 1. Substitute preferences of physicians
- 2. Quality of life measures
- 3. Decision evaluation measures
- 4. Coping measures
- 5. Knowledge measures
- 6. Treatment preferences

Completion date

31/12/2006

Eligibility

Key inclusion criteria

Patients with prostate cancer referred for radiotherapy with curative intent are eligible.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

Key exclusion criteria

Labile personality structure, as assessed by the physicians, and lack of understanding of the Dutch language.

Date of first enrolment

01/01/2001

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

Netherlands

Study participating centre Radboud University Nijmegen MC

Nijmegen Netherlands 6500 HB

Sponsor information

Organisation

Dutch Cancer Society (The Netherlands)

ROR

https://ror.org/0368jnd28

Funder(s)

Funder type

Charity

Funder Name

Dutch Cancer Society

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	20/07/2007		Yes	No