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Development, implementation and evaluation of an integrated follow-up programme for people with cutaneous malignant melanoma

Submission date 25/08/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2005	**Overall study status** Completed	
Last Edited 10/09/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
C10673/A3912

Study information

Scientific Title

Study objectives
Programmes of integrated follow-up co-ordinate activities and resources between primary and secondary care to ensure effective on-going care for patients with specific conditions. This proposal is to develop, implement and evaluate a primary care based integrated follow-up programme for people with cutaneous malignant melanoma. A rigorously evaluated programme for cutaneous malignant melanoma could provide a model for low-tech, efficient, effective and sustainable follow-up programme. Malignant melanoma and primary care have been chosen for the model for several reasons. Melanoma affects both sexes with a disproportionate impact on young people. Most individuals survive for prolonged periods but can experience a recurrence at any time making careful follow-up important. Follow-up consists mainly of clinical examination in contrast to other cancers that need invasive follow-up procedures. Most general practices will have small numbers of patients with melanoma. While this is likely to facilitate primary care based follow-up because of comparatively light workload and resource requirements, it creates challenges in terms of gaining and maintaining expertise.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cutaneous Malignant Melanoma

Interventions

Integrated primary care based follow-up programme for cutaneous malignant melanoma. Intervention comprises general practitioner training, central appointments database, patient education programme, protocol driven reviews in primary care, rapid access pathway to secondary care.

The control group continue to attend follow-up at the Joint Melanoma Clinic, Aberdeen Royal Infirmary. This would be termed 'usual care' as it is the current standard treatment for people treated for melanoma.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Patient satisfaction and adherence to guidelines

Secondary outcome measures
1. Psychological and physical well-being
2. Costs to patients and health services
3. Processes of care

Overall study start date
01/04/2005

Completion date
30/09/2006

Eligibility

Key inclusion criteria
People previously treated for cutaneous malignant melanoma.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Non cutaneous melanoma
2. Active recurrence or a recurrence within the last 12 months
3. Terminally ill

4. Mentally ill
5. If their general practitioner believes them to be otherwise unsuitable for participation in the study

Date of first enrolment
01/04/2005

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
University of Aberdeen
Aberdeen
United Kingdom
AB25 2AY

Sponsor information

Organisation
University of Aberdeen (UK)

Sponsor details
King's College
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United Kingdom
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Sponsor type
University/education

Website
http://www.abdn.ac.uk/idx.php

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK) (ref: C10673/A3912)

Alternative Name(s)
CR_UK, Cancer Research UK - London, CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

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	patient satisfaction results	11/05/2010		Yes	No