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Utility of the skin cancer quality of life impact tool (SCQOLIT)

Submission date	Recruitment status	[_] Prospectively registered
03/02/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/02/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/01/2021	Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02580916

Secondary identifying numbers
20564

Study information

Scientific Title
Use of the Skin Cancer Quality of Life Impact Tool (SCQOLIT) – a feasibility study in non-melanoma skin cancers

Study objectives
The aim of this study is to explore the practicality and value of the Skin Cancer Quality of Life Impact Tool (SCQOLIT) for non-melanoma skin cancer (NMSC) to patients and clinicians in the dermatology clinical setting.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Oxford B Research Ethics Committee, 18/06/2015, ref: 14/SC/1446

Study design
Prospective non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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
Topic: Cancer, Dermatology; Subtopic: Melanoma, Skin (all Subtopics); Disease: Skin, Dermatology

Interventions
Three hundred patients (100 with squamous cell carcinoma, 200 with basal cell carcinoma) identified in Dermatology outpatient clinics will be recruited to complete SCQOLIT questionnaires at baseline (after histological confirmation of NMSC), at 3 months (by postal or face:face) and at 6-9 months (high risk patients only). Structured interviews with twenty patients and focus group work with 10-15 Dermatology staff will establish acceptability of the SCQOLIT and identify any barriers to implementation. Both quantitative and qualitative analyses will be undertaken.

Intervention Type
Other

Primary outcome measure
Acceptability of SCQOLIT tool as determined by analysis of patients participation rates and qualitative analysis of patient and staff preferences at the end of the study.

Secondary outcome measures
Psychometric properties of SCQOLIT tool are measured at baseline, 3 months and 6-9 months.

Overall study start date
01/07/2015

Completion date
30/03/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Participant is willing and able to give informed consent for participation in the study.
3. All patients with a histopathological diagnosis of NMSC (primary or recurrent disease)
4. All treatments used for NMSC will be included in the study; excision, shave excision, curettage and cautery, Mohs micrographic surgery, photodynamic therapy and topical treatments e.g. imiquimod cream

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Total final enrolment
318

Key exclusion criteria
1. Concurrent internal malignancy as this is likely to significantly influence quality of life (QOL)
2. Patients referred on to other specialties for management of their skin cancer e.g. Plastic surgeons / Clinical oncology

3. Other significant dermatological diseases e.g. severe inflammatory or blistering skin conditions as this may influence QOL
4. Inability to consent for themselves

Date of first enrolment
01/07/2015

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Churchill Hospital
Old Road
Headington
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

Sponsor details
Research & Development Office
Joint Research Office
Block 60
Churchill Hospital
Headington
England
United Kingdom
OX3 7LE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Oxfordshire Health Services Research Committee

Results and Publications

Publication and dissemination plan
Results will be disseminated at national and international Dermatology/Skin Cancer meetings and publishing in a high impact peer reviewed journal.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at ISOQOL in :	01/10/2016	29/04/2019	No	No

Abstract results	results presented at the 97th Annual Meeting of the British Association of Dermatologists in :	30/11/2017	29/04/2019	No	No
Results article	results	01/03/2020	04/01/2021	Yes	No
HRA research summary			28/06/2023	No	No