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KeepYouSafe: a bilingual Cancer Care Checklist application

Submission date	Recruitment status	[X] Prospectively registered
16/11/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/11/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/06/2021	Cancer	

Plain English summary of protocol

Background and study aims
Complications of cancer and its treatments are common. Many patients will experience side effects following chemotherapy, radiotherapy or immunological therapies. These lead to morbidity and mortality as well as resource utilisation in communities and hospitals. Complications of cancer and its treatments are predictable (fever, diarrhoea, skin reactions and drug specific effect). Stressed patients, family and friends might not always recognize the need to seek help.
The aim of this study is to show whether patients undergoing treatment for cancer can actively make sure that their treatment is safe by using checklists.

Who can participate?
Adults with cancer, along with one family or friend per patient

What does the study involve?
All participants will be given a smartphone application containing a checklist for common side effects of cancer treatment. They use the app for 60 days and complete questionnaires every 30 days

What are the possible benefits and risks of participating?
Participants may benefit from participating as they might feel extra security after checking for side effects and sharing these with a friend or family member.
Patients will be encouraged to contact health services if they experience side effects. Therefore, a possible risk of participating is that this could lead to over-treatment in some cases.

Where is the study run from?
Betsi Cadwaladr University Health Board, North Wales (UK)

When is the study starting and how long is it expected to run for?
January 2018 to May 2019

Who is funding the study?
iGrant from Tenovus Cancer Care (UK)

Who is the main contact?
Chris Subbe
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Contact information

Type(s)
Public

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
Prospective pilot study of a smart phone application for patients undergoing treatment for cancer

Study objectives
Usage of electronic checklists tailored to the needs of patients with cancer improves reliability and timelines of engagement with their multi-disciplinary team. Earlier diagnosis and treatment of common complications of cancer, chemo- and radio-therapy will lessen the impact on patient related outcome measures and resource utilization.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Board Bangor, 22/06/2018, 18/WA/0213

Study design
Interventional non-randomised feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cancer (solid tumours or haematological)

Interventions
All participants will receive a smartphone application containing a checklist of common side effects of cancer. Participants will be asked to use this app for 60 days and will complete questionnaires every 30 days.

Intervention Type
Behavioural

Primary outcome measure
Usage of application, assessed by number of completed checklists at 60 days from inclusion

Secondary outcome measures
1. Number of appointments during the study period of 60 days, assessed by questionnaires to General Practitioners and assessment of the hospital patient administration system at 60 days from inclusion
2. Number of days in hospital during the study period of 60 days, assessed by review of patient administration system at 60 days from inclusion

Overall study start date
15/01/2018

Completion date
01/05/2019

Eligibility

Key inclusion criteria

Patients:
1. Aged 18 years or older
2. Cancer patient (solid tumour or haematological cancer) and their families
3. Resident of North Wales
4. Under the care of the North Wales Cancer Centre
5. Receiving bestsupportive care, chemotherapy, radiotherapy or immunotherapy
6. Owns and able to use smartphone
7. Provide informed consent

The families or friends (one per patient) of the patients will also be invited to participate:
1. Owns and able to use a smartphone
2. Provide informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50 intervention, 50 control, 50 next of kin / friends

Total final enrolment
150

Key exclusion criteria
1. On an end-of-life pathway
2. Inability to consent

Date of first enrolment
01/12/2018

Date of final enrolment
01/03/2019

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre

Ysbyty Gwynedd
Penrhosgarnedd
Bangor
United Kingdom
LL57 2PW

Study participating centre
Ysbyty Glan Clwyd
Rhuddlan Road
St Asaph
United Kingdom
LL18 5UJ

Sponsor information

Organisation
BCU HB

Sponsor details
Penrhosgarnedd
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LL57
01248384384
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Sponsor type
Hospital/treatment centre

Website
http://www.wales.nhs.uk/sitesplus/861/page/41562

ROR
https://ror.org/03awsb125

Funder(s)

Funder type
Charity

Funder Name

Tenovus

Alternative Name(s)
Tenovus Cancer Care

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Publication intended in July 2019, after completion of the trial

Intention to publish date
01/07/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to potential commercial sensitivities.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/09/2020	04/06/2021	Yes	No
HRA research summary			28/06/2023	No	No