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Randomised controlled trial of Vinehealth® digital health cancer solution

Submission date
11/08/2021

Recruitment status
No longer recruiting

Registration date
15/06/2022

Overall study status
Completed

Last Edited
24/01/2025

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chemotherapy is a common treatment for people with cancer. It can be associated with a number of side effects and symptoms, which if not adequately managed can have a negative impact on the lives of people living with cancer. Chemotherapy is often delivered on an outpatient basis and most people have to manage the side effects of their treatment at home, with limited input from health professionals. Therefore, it is important to look at ways of supporting people receiving chemotherapy to manage their symptoms and therefore improve their quality of life during periods when they are at home.
Researchers are conducting a large trial in 240 people to evaluate the impact of the use of the Vinehealth® app to help manage symptoms and side effects and hopefully improve the quality of life of people with breast, bowel or lung cancer. This is for patients who have just had surgery for their cancer and are about to start chemotherapy as part of their treatment for their cancer. Participation will last for 24 weeks.
The main aim of the trial is to see if using the Vinehealth® app in addition to usual care is better or worse than usual care on its own in the reporting and management of chemotherapy-related symptoms to help improve quality of life in the 24 weeks from the start of chemotherapy treatment.

Who can participate?
Patients aged 18 years or over who have had surgery for their cancer and are about to begin at least 12 weeks of chemotherapy treatment for their cancer

What does the study involve?
Once eligibility is confirmed patients will be randomly allocated into two groups using an online randomisation platform. One group will use the Vinehealth® app to log symptoms, complete questionnaires and find information for self-management, whilst the other group will complete questionnaires on paper and receive care that is usually provided at their hospital. Patients will participate in the trial for 24 weeks during their chemotherapy treatment period.
The groups that patients will be allocated into will be selected by a computer, which has no information about the individual, so people will be selected by chance. Patients in both groups

will have their quality of life compared to see if one is better than the other. Other information, such as symptoms, other outcomes, supportive care needs, work limitations, confidence in their ability to complete tasks, and anxiety, will also be compared across both groups.

What are the possible benefits and risks of participating?
If allocated to the 'Vinehealth® app' group, the possible benefits of participating are that during chemotherapy whilst at home, the collection of patient-reported outcomes and articles/self-help information participants are able to access via the app may help some people to self-manage their medications, side-effects, symptoms and also help some participants with their quality of life, reduce the need for emergency care and improve cancer survival. In addition, on the app there is a library of helpful information for people undergoing chemotherapy, such as advice on feelings and emotions and living with and beyond cancer. Participants will also have a list of important contacts on the app, such as patient support organisations and contact details of care teams. The care team will have access to the information that is logged in the app via a clinician section of the app called VinehealthPRO®. This may aid discussion of the symptoms experienced by some participants at home when visiting the care team at the hospital.
If participants are allocated to the 'usual care' group, some participants may not experience any direct benefits of participating in this trial. However, the information and feedback provided from this trial may be beneficial for other patients with cancer in the future as it will help the researchers to understand the impact of the 'Vinehealth® app' as they will compare the symptoms and the information from people in the app group and the 'usual care' group.
The overall results of the trial will be used to provide information to determine whether the use of the Vinehealth® app is better or worse than usual care at improving quality of life whilst participants are having chemotherapy treatment for their cancer.

Where is the study run from?
Surrey Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
March 2021 to March 2024

Who is funding the study?
UK Research and Innovation (UKRI)

Who is the main contact?
Dr Agnieszka Michael
a.michael@surrey.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Agnieszka Michael

ORCID ID
https://orcid.org/0000-0002-7262-6227

Contact details

Clinical Research Building
Egerton Road
Guildford
United Kingdom
GU2 7XP
+44 (0)1483688546
a.michael@surrey.ac.uk

Type(s)
Scientific

Contact name
Dr Luke Smith

Contact details
Surrey Clinical Trials Unit
Egerton Road
Guildford
United Kingdom
GU2 7XP
+44 (0)1483 689797
luke.smith@surrey.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
300753

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51820, IRAS 300753, CTU-058/Vinehealth

Study information

Scientific Title
Multi-centre randomised controlled trial of Vinehealth® digital health cancer solution for cancer patients commencing chemotherapy

Acronym
CTU-058/Vinehealth

Study objectives
The primary objective is to see if it is possible to undertake a sufficiently large enough randomised controlled trial (RCT) and provide robust evaluation claims that Vinehealth's digital platform (the app) can effectively demonstrate improvement in quality of life over standard of

care by use of the platform. This will be measured using health-related quality of life (QOL) measured by FACT-G (PWB) over 24 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/03/2022, East of Scotland Research Ethics Serivce (EoSRES, Tayside Medical Science Centre, Residency Block, Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; +44 (0)1382 383848; tay.eosres@nhs.scot), ref: LR/AG22/ES/0007

Study design
Multi-centre two-arm parallel-group randomized controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Colorectal, breast and lung cancer patients commencing adjuvant systemic treatment

Interventions
180 colorectal, breast and lung cancer patients commencing adjuvant systemic treatment (chemotherapy+/-targeted therapies) will be enrolled into a prospective, multi-centre two-arm parallel-group RCT over 24 weeks. Patients starting chemotherapy will be recruited across several clinical sites from outpatient oncology clinics and monitored for 24 weeks total. All patients will be randomised 1:1 using an online randomisation service (SealedEnvelope.com) to minimise allocation bias to (a) current standard of care or (b) current standard of care plus the addition of the Vinehealth® platform. Randomisation will be stratified by centre and cancer type.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vinehealth digital app

Primary outcome(s)
1. Health-related QoL measured using FACT-G (PWB) at baseline, (then 6, 12, 18) and 24 weeks

Key secondary outcome(s))
1.1. Patient compliance with patient-reported outcome (PRO) data collection measured using FACT-G (PWB), EQ5D, QLQ-C30 at baseline, then 6, 12, 18 and 24 weeks
1.2. Patient self-management of symptoms measured using EQ-5D-5L and EORTC QLQ-C30 at baseline, then 6, 12, 18 and 24 weeks
2. Process of care and emergency healthcare utilisation (medication adherence, A&E/GP visits

/admissions, acute oncology hotline utilisation, concomitant medications) measured by asking participants (at their clinic visits) and reviewing their medical records at baseline, then 6, 12, 18 and 24 weeks

Completion date
31/03/2024

Eligibility

Key inclusion criteria
Patients with breast, colorectal and lung cancer who have just had surgery for their primary cancer and are about to commence adjuvant chemotherapy as part of their treatment will be approached in oncology clinics to see if they would like to participate:
1. Adults (age >18 years) commencing adjuvant cytotoxic chemotherapy at participating site for the minimum planned duration of 12 weeks
2. Breast, colorectal or lung cancer diagnosis
3. Primary disease completely excised R0 with no evidence of macroscopic residual or metastatic disease
4. Smartphone access that conforms to the following specifications:
4.1. Apple devices running iOS 9.2 (or later) or devices running Android 4.4 (or later)
4.2. Screen size of at least 4.7 inches (equivalent to an iPhone 6)
5. Able to read and write in English (Information will be provided in the Welsh language if requested for the Welsh site)
6. Able to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
174

Key exclusion criteria
1. Systemic anti-cancer treatment to palliate incurable cancer for this malignancy
2. No longer undergoing systemic therapy
3. No smartphone access
4. Unable to read or write in English
5. Significant cognitive impairment

Date of first enrolment
17/06/2022

Date of final enrolment
03/10/2023

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
University College London Hospital
250 Euston Road
London
United Kingdom
NW1 2PG

Study participating centre
Queens Hospital
Rom Valley Way
Romford
United Kingdom
RM7 0AG

Study participating centre
Prince Philip Hospital
Bryngwyn Mawr, Dafen
Llanelli
United Kingdom
SA14 8QF

Sponsor information

Organisation
University of Surrey

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Research organisation

Funder Name
UK Research and Innovation

Alternative Name(s)
UKRI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Luke Smith (Luke.Smith@surrey.ac.uk). Data collected: quantitative analysis of the following data: cancer diagnosis, cancer stage, type of cancer, concomitant medication, chemotherapy plan and treatment to date: FACT-G (PWB), EQ-5D and QLQ-C30, current medication - chemotherapy dose reductions/delays and reasons, A/E and GP attendance and advice, chemotherapy hotline utilisation and advice.
All of the above data will be collected at baseline and then 6 weekly at 6, 12, 18 and 24 weeks. Qualitative data will be obtained in the form of interviews mid-way through and following the end of the trial after 24 weeks from a sample of participants.
Data will be available following publication. A data-sharing agreement is currently being drawn up. All trial analyses will be according to the Statistical Analysis Plan (SAP), which will be prepared before the first substantive unblinded analysis and agreed in advance by the Trial Steering Committee (TSC). A single main analysis will be performed at the end of the trial when follow-up is complete. Written informed consent will be obtained from participants. All participants will receive a randomisation number which will replace the participant's name and provide anonymisation. Participants will not be identified in the results of the study.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Poster results			24/01/2025	No	No
Protocol file	version 1.6	06/07/2023	07/12/2023	No	No