

Randomised controlled trial of Vinehealth® digital health cancer solution

Submission date 11/08/2021	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 15/06/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/01/2025	Condition category Cancer	<input type="checkbox"/> 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

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Contact information

Type(s)

Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

300753

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 Service (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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Final version not available yet

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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2021

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

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

England

United Kingdom

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

Sponsor details

Research Integrity & Governance Office (RIGO)

Senate House

Guildford

England

United Kingdom

GU2 7XH

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rigo@surrey.ac.uk

Sponsor type

University/education

Website

<https://surreynet.surrey.ac.uk/research-integrity-and-governance>

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

Publication and dissemination plan

A detailed publication plan will be developed and approved by the Trial Management Group (TMG), specifying what publications are planned and the person responsible for each. A writing committee will be established for each planned publication, being a subgroup of the TMG. Through peer-reviewed publications and presentations at policy and academic meetings, the findings will be disseminated widely. The results of the trial will be disseminated regardless of the direction of effect.

On completion of the trial, the data will be analysed and tabulated and a final study report prepared. These results will be summarised on relevant trial registries, and a manuscript summarizing the main trial results will be submitted to a relevant medical journal within 12 months of trial completion, with authorship according to the criteria defined by the International Committee of Medical Journal Editors (ICMJE) (<http://www.icmje.org>). These state that authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. The results of this trial will also be publicised through the Surrey Clinical Trials Unit (CTU), the University of Surrey and Vinehealth's website and App, and using social media.

Intention to publish date

30/09/2024

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	version 1.6	06/07/2023	26/07/2023	No	No
Protocol file			07/12/2023	No	No
Poster results			24/01/2025	No	No