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Trial of an app to support breast cancer survivors prescribed hormone therapy

Submission date
08/10/2018

Recruitment status
No longer recruiting

Registration date
09/10/2018

Overall study status
Completed

Last Edited
22/06/2020

Condition category
Cancer

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Hormone therapy (HT) is prescribed to breast cancer survivors after they have completed primary treatment. It can significantly reduce the risk of breast cancer recurrence and mortality. However, many women do not take their treatment as prescribed, which is known as non-adherence. This leads to significantly increased risk of recurrence and mortality. Despite sub-optimal levels of adherence and the importance of adherence in clinical outcomes, no studies have attempted to improve adherence to tamoxifen. This study will test a digital intervention (app) which has been developed and tested as part of a previous study, where it was shown to be acceptable and had the potential to improve adherence.

Who can participate?
Women diagnosed with primary breast cancer who have been prescribed hormonal therapy within the last three years

What does the study involve?
Phase 1 is a large questionnaire study to investigate predictors of non-adherence and uptake of the intervention. From there, participants are invited into phase 2 and randomly allocated to the intervention or wait-list control group. Participants in the intervention group receive access to the app and work through the 6 sessions over a 9 week period. The app aims to provide information on how HT works and why women have been prescribed it; to help women develop strategies to remember to take HT; to address any concerns associated with HT; and to help women to manage their side effects. Participants also receive two telephone support sessions from a researcher. Participants in the wait list control group receive access to the app after 12 months. All participants complete questionnaires at the start of the study and 9 weeks, 6 months and 12 months later to measure adherence to treatment.

What are the possible benefits and risks of participating?
The results will establish the effectiveness of this intervention at improving adherence and supporting patients with the treatment. Participants should benefit by taking part as they will receive access to the app which has been designed to help them with their treatment and to improve their adherence and their quality of life. There is very little risk involved in participating. A participant could become distressed after reading the information about their treatment.

They will be encouraged to discuss their concerns with their healthcare team and will be referred to support services.

Where is the study run from?
1. Pinderfields Hospital
2. Pontefract Hospital
3. Dewsbury and District Hospital
4. Huddersfield Royal Infirmary
5. Calderdale Royal Hospital
6. Darlington Memorial Hospital
7. Bishop Auckland General Hospital
8. University Hospital of North Durham
9. City Hospital
10. Tameside General Hospital
11. Wythenshawe Hospital
12. Macclesfield District General Hospital
13. Burnley General Hospital
14. Royal Blackburn Hospital
15. Conquest Hospital
16. Eastbourne District General Hospital
17. Whittington Hospital
18. St Albans City Hospital
19. University College Hospital
20. Barnet Hospital
21. Chase Farm Hospital
22. Royal Free Hospital
23. Bronglais General Hospital
24. Withybush General Hospital
25. Prince Philip Hospital

When is the study starting and how long is it expected to run for?
January 2018 to July 2021

Who is funding the study?
Breast Cancer Now

Who is the main contact?
Dr Zoe Moon
zoe.moon@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Zoe Moon

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
38697

Study information

Scientific Title
Randomised controlled trial of an app-based digital intervention to support breast cancer survivors prescribed hormone therapy (e-path study)

Acronym
e-path study

Study objectives
The aim of the trial is to assess the effectiveness of an app to improve adherence and secondary outcomes including quality of life in breast cancer survivors prescribed hormone therapy. The app was developed and piloted as part of a previous study (16/LO/1205). The results from the pilot study showed the intervention was acceptable, and that it had the potential to improve adherence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/11/2018, London - City & East Research Ethics Committee (Bristol Research Ethics Committee Centre, Whitefriars, Level 3, Block B, Lewins Mead, Bristol, BS1 2NT; +44(0)207 1048058;
nrescommittee.london-cityandeast@nhs.net), ref: 18/LO/1674.

Study design
Randomised; Both; Design type: Treatment, Education or Self-Management, Psychological & Behavioural, Cross-sectional

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Breast cancer

Interventions
There are two phases to the current study.

Phase one: A large questionnaire study of around 2000 women will measure adherence and a range of psychosocial variables. Patients will be recruited from outpatient clinics across the UK. Eligible patients will be identified by clinic staff and given an information sheet as well as verbal information about the study. They will be encouraged to contact the research team if they have any questions. The questionnaire can be completed in clinic or at home either as a paper version or online. Informed consent will be taken before the patient completes the questionnaire. Participants who are not eligible for phase 2 will be followed up at 6 and 12 months with a short questionnaire to establish if it is possible to identify who will later become non-adherent using the psychosocial measures collected at baseline.

Phase two: Women from phase one who are eligible (n=220) will be invited into the RCT to test the effectiveness of the digital intervention. Patients will be randomised 1:1 into the intervention or wait list control conditions. Patients in the wait list control condition will receive access to the intervention materials at 12 months follow up. All patients will complete a questionnaire pack at 9 weeks, 6 months and 12 months post randomisation. Patients in the intervention group will receive access to the app and will work through the 6 sessions over a 9 week period. They will receive two telephone support sessions from a researcher. At 9 weeks and 12 months, a proportion of the intervention group will be invited to take part in a qualitative study to discuss their experiences of the intervention. The 12 month follow up will be a qualitative online survey.

Intervention Type
Other

Primary outcome measure
Adherence, measured using the MARS. Women be classified as adherent or non-adherent based on their scores on the MARS; Timepoint(s): baseline, 9 weeks, 6 months and 12 months.

Secondary outcome measures

1. Beliefs about hormone therapy, measured using BMQ-AET
2. Illness perceptions, measured using IPQ-BCS
3. Distress, measured using PHQ2, GAD7
4. Quality of life, measured using FACT-B
5. Side effects, measured using BCPT Symptom checklist
6. Satisfaction with information about treatment measured using The Satisfaction with Information about Medicines Scale (SIMS)
7. Self-efficacy for managing symptoms measured using a modified version of a standard self-efficacy scale
8. Perceived behavioural control measured using 4 items from a Theory of Planned Behaviour questionnaire
All measures are collected at baseline, 9 weeks, 6 months and 12 months

Overall study start date
08/01/2018

Completion date
31/07/2021

Eligibility

Key inclusion criteria
Phase one:
1. Diagnosed with primary breast cancer
2. Prescribed hormonal therapy within the last three years

Phase two:
1. ≤23 on the MARS
2. Has weekly access to smartphone or tablet
3. Has email address

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 2000; UK Sample Size: 2000

Key exclusion criteria
1. Diagnosed with secondary or metastatic cancer
2. Prescribed duration of hormonal therapy is due to come to an end during trial
3. Current treatment for depression or psychiatric disorders
4. Not fluent in verbal and written English

Phase two:
1. Diagnosed with secondary or metastatic cancer
2. Prescribed duration of hormonal therapy is due to come to an end during trial
3. Current treatment for depression or psychiatric disorders
4. Not fluent in verbal and written English
5. Patient does not provide consent or refuses to be randomised
6. Patient is currently taking part in another trial

Date of first enrolment
08/01/2019

Date of final enrolment
21/12/2019

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Guy's Hospital (lead centre)
London
United Kingdom
SE1 9RT

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Pontefract Hospital
Friarwood Lane
Pontefract
United Kingdom
WF8 1PL

Study participating centre
Dewsbury and District Hospital
Halifax Road
Dewsbury
United Kingdom
WF13 4HS

Study participating centre
Huddersfield Royal Infirmary
Acre St
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
Calderdale Royal Hospital
Salterhebble
Halifax
United Kingdom
HX3 0PW

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
Bishop Auckland General Hospital
Cockton Hill Rd
Bishop Auckland
United Kingdom
DL14 6AD

Study participating centre
University Hospital of North Durham
North Road

Durham
United Kingdom
DH1 5TW

Study participating centre
City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Study participating centre
Tameside General Hospital
Fountain Street
Ashton-under-Lyne
United Kingdom
OL6 9RW

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Macclesfield District General Hospital
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
Burnley General Hospital
Casterton Avenue
Burnley
United Kingdom
BB10 2PQ

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
Conquest Hospital
The Ridge
Hastings
St Leonard's-on-Sea
United Kingdom
TN37 7RD

Study participating centre
Eastbourne District General Hospital
Kings Drive
Eastbourne
United Kingdom
BN21 2UD

Study participating centre
Whittington Hospital
Magdala Ave
London
United Kingdom
N19 5NF

Study participating centre
St Albans City Hospital
Waverley Road
St Albans
United Kingdom
AL3 5PN

Study participating centre
University College Hospital
235 Euston Road
Fitzrovia

London
United Kingdom
NW1 2BU

Study participating centre
Barnet Hospital
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Study participating centre
Chase Farm Hospital
127 The Ridgeway
Enfield
United Kingdom
EN2 8JL

Study participating centre
Royal Free Hospital
Pond St
Hampstead
London
United Kingdom
NW3 2QG.

Study participating centre
Bronglais General Hospital
Caradoc Road
Aberystwyth
United Kingdom
SU23 1ER

Study participating centre
Withybush General Hospital
Fishguard Road
Haverfordwest
United Kingdom
SA61 2PZ

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

Sponsor information

Organisation
King’s College London and Guy’s and St Thomas’ NHS Trust

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Breast Cancer Now; Grant Codes: 2017MayPR881l

Alternative Name(s)
BCN

Funding Body Type

Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Main study outcomes will be published in a high impact peer reviewed journal in 2020.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
Reasonable requests for data will be can be made to the principal investigator for consideration.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No