

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

|                                        |                                                   |                                                                                                              |
|----------------------------------------|---------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>08/10/2018   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>09/10/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>22/06/2020       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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

**ORCID ID**  
<https://orcid.org/0000-0002-5242-1718>

**Contact details**

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Guy's Hospital  
London  
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SE1 9RT  
+44 (0)207 188 0179  
zoe.moon@kcl.ac.uk

**Additional identifiers****Protocol serial number**

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.

**Primary study design**

Interventional

**Study design**

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

**Study type(s)**

Treatment

**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(s)

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.

### Key secondary outcome(s)

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

### 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.  $\leq 23$  on the MARS
2. Has weekly access to smartphone or tablet
3. Has email address

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

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

**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

**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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |