PEPSIN

*P*sychobiological *E*ffects of *P*ersonalised *S*upportive *IN*terventions: a feasibility study

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Background

Patients with breast cancer often participate in activities such as make-up workshops, mindfulness or exercise classes that help them cope with disease and treatment, while reducing symptoms of stress.

As well as improving general well-being there is some laboratory evidence that reducing stress cortisol levels may impact on cancer cell proliferation and perhaps improve treatment outcomes.

Psychological well-being can be assessed with questionnaires. Some biological changes can be measured through saliva or hair.

Aims

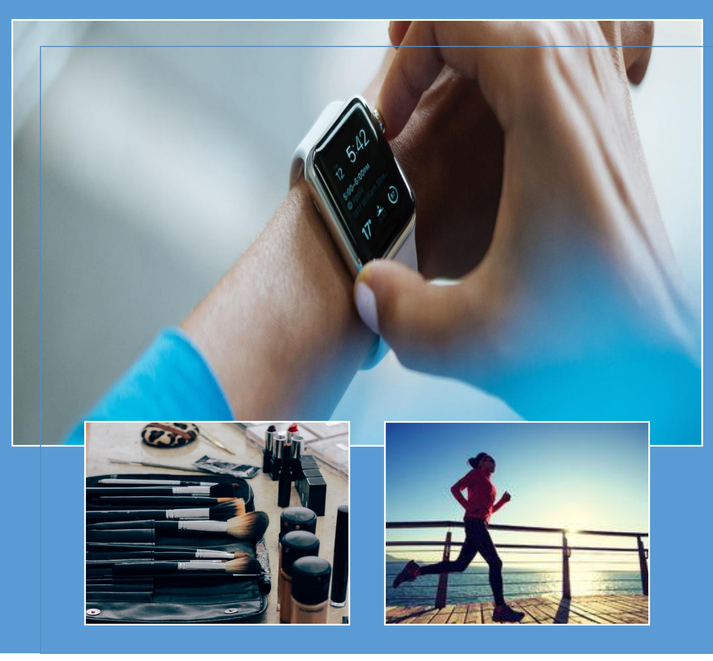
The primary aim of PEPSIN is to assess the feasibility and acceptability of using psychological and biological measures in the evaluation of a stress reduction programme within the breast cancer setting

As a secondary aim we will assess changes in psychological and biological wellbeing

Recruitment

- 40 women with early stage breast cancer about to start either a:
  - Supportive exercise programme tailored to people with cancer

  or
  - 'Look Good Feel Better' workshop teaching women about skin care and make up during and after cancer treatment



Eligibility

- Women with early stage breast cancer
- 18 or older
- Able to provide consent and read and speak English
- No previous or current participation in the chosen supportive intervention
- No prior history of clinical depression or anxiety

Methods

- Recruitment will be via Participant Identification Centres (PICs)
- Participants will complete PROs and provide biological samples over 12 weeks (see flow chart)

Referral centre identifies potential participant, provides them with a PEPSIN information pack and informs SHORE-C

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SHORE-C contacts individual at least 24 hours later. If individual is interested, researchers receive consent

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Participant completes baseline measures returning questionnaires to SHORE-C and biological materials to the University of Brighton

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Participants are contacted prior to their 6 and 12 week follow up points to ensure continued consent for study and selected biological collections

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Prior to 12 week follow up, an end of study telephone interview is scheduled

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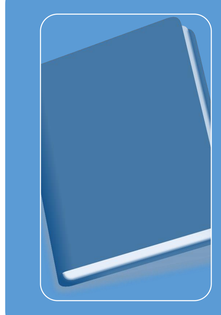
Telephone interview with SHORE-C to discuss the measures used, how long they took, and the acceptability of potential future measures

Measurements

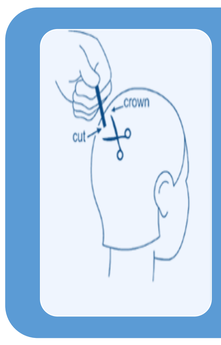


Psychological Wellbeing

- FACT-B
- Perceived Stress Scale
- Body Image Scale
- Rosenberg Self-Esteem Scale
- Completed at baseline, day of intervention, 6 and 12 weeks follow up

Optional Saliva Samples

- Baseline samples twice a day for 6 days including day of intervention
- Follow up samples twice a day for 3 days at 6 and 12 weeks
- Participants record collection time, dietary details and medication use



Optional Hair Samples

- Baseline sample 3 days before intervention
- Follow up sample at 6 and 12 weeks
- Samples consist of 5-20 strands

Analysis

All questionnaires returned to SHORE-C will be analysed for changes in well being as well as correlation with stress cortisol levels

The end of study interview will inform potential future studies and measures

Biological samples returned directly to the University of Brighton

- Saliva and hair analysed for any changes in cortisol levels by Enzyme Immune Assay
- Saliva may also be used to measure pro-inflammatory and anti-inflammatory cytokines using ELISA

Estimates of non-adherence and completion rates will be generated to inform power calculations for future studies

Next Steps

Plans for a future study to be determined including the types of measures that may be used based on patient feedback

Ethics Statement

PEPSIN was reviewed and approved by the Brighton and Sussex Medical School Research Governance Committee along with the Health Resource Authority and the South Central - Berkshire Research Ethics Committee (17/SC/0170)

Acknowledgements

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