Methods: The multinational EFFECT study, including 355 women (and 2 men) with mBC from 5 European countries and Australia, randomly assigned participants to either usual care (UC) or a 9-month supervised exercise program (EX) combining aerobic, resistance, and balance exercises. All participants received general exercise advice and an activity tracker. Breast cancer-specific symptoms (EORTC QLQ-BR45) were assessed at baseline, 3, 6 (primary timepoint), and 9 months. Intervention effects were analyzed on an intent-to-treat basis with mixed models for repeated measures, adjusted for baseline values of the outcome variable and stratification factors (line of treatment and study center).

Results: Female participants had a mean ± SD age of 55.4 ± 11.1 years, mostly received 1st/second-line treatment at study enrollment (74.8%) and had bone metastases (67.5%). At baseline, sexual functioning (17.1±21.2) was low, associated with older age and depressive symptoms. Almost half of sexually active women reported little sexual enjoyment, 26% of all participants reported moderate-to-severe endocrine sexual symptoms and 24% a poor body image. Exercise improved sexual functioning (effect size (ES)=0.28, p=.0031) and endocrine sexual symptoms (ES=0.25, p=.0026) at 6-month. The exercise effect on sexual functioning was sustained at 9-month (ES=0.23, p=.020).

Conclusions: Women with mBC are likely to experience sexual problems and may have an impaired body image. Exercise can help improve sexual health in these patients. Further research should determine the optimal role of exercise in addressing symptom burden, possibly in conjunction with additional support.

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Legal entity responsible for the study: PREFERABLE consortium.

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270MO An international update of the EORTC questionnaire for assessing quality of life in breast cancer patients: Results of the validation study phase IV EORTC QLQ-BR42

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Background: The EORTC QLQ-BR23, developed in 1996, was one of the first disease-specific questionnaires, to assess quality of life (QoL) in patients with breast cancer (BC). However, since 1996, major changes in BC treatment have occurred, requiring updating of the EORTC BC module. The results of phase I-III were presented at the ESMO Meeting 2018. This abstract presents the final phase IV validation study of the updated version, the EORTC QLQ-BR42.

Methods: The update of the EORTC QLQ-BR23 module followed standard EORTC guidelines.Developmental phase I-II, a systematic literature review followed by interviews with patients and health care providers, resulted in 15 QoL issues transformed into 27 items relevant for BC patients. The preliminary module of 27 items was pre-tested in phase III toassess their perceived importance and acceptability. Phase IV was designed to assess the psychometric properties of the questionnaire in an international field study. Data of all patients were usedfor psychometric analyses, i.e., the evaluation of the scale structure, internal consistency, test-retest reliability, convergent, discriminant, and clinical validity, and responsiveness to change. The study was registered on clinicaltrials.gov database (NCT04270123).

Results: Between May 2019 and September 2021, 576 patients from 17 countries (16 different languages) were enrolled in the international phase IV validation study. The psychometric analyses resulted in a final questionnaire containing 42 items divided into ten scales: Breast Symptoms, Body Image, Sexual Functioning, Arm Symptoms, Systemic Chemotherapy Side Effects, Skin Toxicity/Neuropathy, Musculo/Skeletal Symptoms, Endocrine-related Symptoms, Breast Satisfaction, Vaginal Symptoms, and 3 single items: Weight Gain, Sexual Enjoyment and Future Perspective.

Conclusions: The EORTC QLQ BR42 is a revised and innovative module that incorporates the original BR23 items that remain relevant, combined with 19 new items that address the side effects of therapies developed over the past 20 years. This comprehensive module is well suited to assess the QoL of BC patients in future trials.

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Legal entity responsible for the study: EORTC QOL Group.

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272P Evaluating a digital tool for supporting people affected by breast cancer: A prospective randomised controlled trial - The ADAPT study

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Background: OWise Breast Cancer is a digital tool for supported self-management in people affected by breast cancer. This study reports the findings from the ADAPT randomized controlled trial (RCT), concerning the impact of OWise on patient activation (Patient Activation Measure, PAM-13) as the primary outcome, with health-related quality of life (HRQoL, European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire, EORTC QLQ-C30), and health status (EuroQol 5-Dimension 5-Level questionnaire, EQ-5D-5L) as secondary outcomes.

Methods: Women with early-stage breast cancer were randomly assigned to standard care (control) or standard care in addition to OWise (intervention). Data were collected using a demographic questionnaire, the PAM-13, the EORTC QLQ-C30, and the EQ-5D-5L at baseline, six weeks, three months, six months, and one year from diagnosis. Linear mixed effect model regression was used to assess the effect of OWise over the first year from diagnosis while correcting for intra-participant correlation.

Results: A total of 166 participants were included, with 85 being randomized into the intervention. No significant differences (p>0.05) in the PAM13 scores, EORTC QLQ-C30 (global QoL, physical functioning, emotional functioning, pain, and fatigue), and EQ-5D-5L index between the control and intervention group were observed over time. It is important to note that there was significant non-adherence to using OWise among the intervention group.

Conclusions: OWise had no statistically significant impact on patient activation, HRQoL, and health status over time compared to standard care alone. Future research should focus on identifying and addressing barriers to digital tool engagement to improve efficacy.

Clinical trial identification: NCT03866655; on 7 March 2019.

Legal entity responsible for the study: The authors.

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