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ORIGINAL ARTICLE

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# Open access follow-up care for early breast cancer: a randomised controlled quality of life analysis

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This study evaluated the acceptability of a supportive model of follow-up. One hundred and twelve women recovering from breast cancer were randomised to receive standard breast clinic aftercare (Control $n$ = 56) or on demand by open access aftercare by breast care nurses (Intervention $n$ = 56). Participants attended a support-based psycho-educational programme delivered in four half-day group sessions. Three quality of life questionnaires (EORTC QLQ-C30, QLQ-BR23, HADS) were administered at baseline and 6-monthly intervals for 2 years. Multilevel linear regression modelling methods were used for evaluation. Age was found to be a statistically significant predictor of quality of life in several sub-scales. Increasing age was negatively associated with sexual functioning, systematic therapy side effects and physical functioning, and positively associated with future perspective. Aftercare assignment was not found to be a statistically significant predictor. Women treated for early breast cancer were not disadvantaged by allocation to the open access supportive care model in terms of quality of life experienced. The model for follow-up was demonstrated to be a feasible alternative to routinised hospital-based follow-up and adds to the evidence for stratified follow-up for low-risk cancer patients, incorporating self-management education. Stratified follow-up pathways are viewed as a preferable approach.

**KEYWORDS**
breast cancer, psychological, quality of life, supportive care

## 1 | INTRODUCTION

The main purpose of routine follow-up care, after potentially curative treatment for early breast cancer, is to monitor for local recurrence, manage the late effects of treatment and provide information, support and reassurance for patients. In the past, many women treated for breast cancer received hospital follow-up for life. At the time of the study current practice across the Yorkshire Cancer Network, UK was to provide follow-up for 5 years after completion of primary therapy; women may attend from 7 to 17 appointments over this period. The value of this resource intensive practice has been questioned for many years (Beaver & Luker, 2005; Gulliford, Opomu, Wilson, Hanham, & Epstein, 1997; Moschetti, Cinuini, Lambertini, Levaggi, & Liberati,

This is a report of a study that compared the acceptability of an open access, supportive model of follow-up care to women treated for Stage 1 or Stage 2 breast cancer. The innovative model is presented as a feasible alternative to hospital-based follow-up, which provides reassurance, self-management education and prompt access to health care practitioners, if and when required. Quality of Life indicators were used to evaluate and demonstrate feasibility, which was supported.

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2016; Taggart, Donnelly, & Dunn, 2012). It had been acknowledged that routine hospital visits of asymptomatic breast cancer patients can be stressful to patients and serve no clinical benefit, apart from providing a platform for annual mammography (Puglisi et al., 2014). Symptoms attributable to local recurrence are more commonly identified by the patient in the interval between clinic visits (Montgomery, 2009), or in general practice (Moschetti et al., 2016). Yet, the practice of regular follow-up in breast clinics of essentially well women had become an entrenched practice in the UK contributing to health service burden and potentially lengthening waiting times for new referrals. Follow-up in breast cancer care was addressed in the National Institute for Clinical Guidelines (NICE, 2009) for Early and Locally Advanced Breast Cancer: Diagnosis and Treatment with the recommendation that follow-up after treatment should be discussed with patients and an agreed care plan documented. The guideline proposed that mammograms should be offered annually for 5 years and then every 3 years after the age of 50 as part of the national screening programme. NICE (2009) indicated clinical follow-up could be provided by primary, secondary or through shared care. This guideline was a major breakthrough that added further weight to the growing belief amongst health care practitioners that routine hospital follow-up failed to meet the self-management and informational needs of all breast cancer patients (NCSI, 2013; NICE, 2009).

The value of routine hospital follow-up as medical surveillance with the primary objective of finding and treating local recurrence or new breast cancers was questioned unsurprisingly given the lack of evidence of significantly improved survival outcomes or palliation as a result of early detection of metastatic disease. The lifetime risk of local recurrence in a previously treated breast with low-risk disease has been reported as 1% at Year 1 increasing to 5% at Years 3 and 4 (Wheeler, Stenning, Negus, Picken, & Metcalfe, 1999). This indicated that intensive early follow-up provided little clinical gain as few women were likely to relapse within this time period. Clinical examination has been shown to detect relatively few relapses in the conserved breast and had a lower sensitivity than mammography (Geurts et al., 2012). However, the risk of contra-lateral breast cancer was 3–5 times greater than that of the general population risk of developing a breast cancer. These risks endorse the need for some form of surveillance to detect and treat the disease before survival is compromised.

Interestingly, the majority of local recurrences, interval cancer, identified between hospital visits are detected by women themselves (Churn & Kelly, 2001; Jack, Kerr, & Kunkler, 1998). Unsurprisingly, studies have demonstrated that many patients are willing, and often do, take responsibility for seeking medical attention in the event of symptoms (Gulliford et al., 1997; O'Mahony, Hegarty, & McCarthy, 2011).

From the perspective of the healthcare professional, women who have had breast cancer are primarily concerned about recurrence, yet many may have information and support needs that coexist (Armes et al., 2009; Elliott et al., 2011; Khan, Mant, Carpenter, Forman, & Rose, 2011), which should to be addressed as well. Armes et al. (2009) reported that after 6 months, 20% of women have five or more unmet needs, and these were frequently the fear of recurrence and psychological in nature. There is evidence that patients want access to advice about any symptoms or concerns, preferably from a clinician they know (Durif-Bruckert et al., 2015). Patients experiencing symptoms necessitating urgent assessment and/or treatment should also have access to systems providing rapid access to specialist breast and oncology services. Specialist nurses, skilled in providing information and support, have successfully provided telephone follow-up services for cancer patients and provided triage to assess and manage new symptoms (Cox & Wilson, 2003; Koinberg, Fridlund, Engholm, & Holmberg, 2004). More recently Shewbridge et al. (2014) have evaluated the delivery of a nurse-led end of treatment consultation clinic for women who have completed treatment for early breast cancer. This reported favourable outcomes for nurses in developing new consultation skills and confidence in addressing previously unmet patient needs and patient acceptability.

Some women access support beyond the scope of NHS provision, e.g. complementary therapies or peer support from other patients. National cancer charities, such as Breast Cancer Care and Macmillan Cancer Support are also providing well-received information and support services to aid self-management (Breast Cancer Care, 2011; Scanlon, Reed, Wray, & Fenlon, 2011; Scanlon & Tilki, 2006) and potentially could be more formally incorporated as co-partners in providing a "Recovery Package", as recommended by the National Cancer Survivorship Initiative (NCSI) and endorsed by government policy. The most recent national cancer strategy Independent Cancer Taskforce, (Cancer Research UK, 2015) identified the need for NHS service providers to provide cancer patients with easier access to information, both during and post-treatment, about what support is available to them.

Follow-up is also intended to provide psychological assessment and support for women recovering from breast cancer as psychological morbidities, such as anxiety and depression, are common in this patient group. Clinic attendances have been associated with increased anxiety as for some it revisits the feelings engendered during diagnosis and enhance concerns about the threat of recurrence particularly if they share a waiting room with women with active and advanced disease (King, Brooks, Featherstone, & Topping, 2014). Health reassurance is commonly offered as the main benefit that patients derive from check-ups but for anxious patients this may be counterproductive (Stark et al., 2004).

The goal of many patients is to get "back to normal" as soon as possible after their cancer treatment but Harvey (2009), a clinical psychologist who has a wealth of experience working with people who have cancer, believes a period of recuperation, convalescence and rehabilitation is needed first. He postulates that "normal" life is not the same as it was before the cancer diagnosis and those patients need to learn new skills to help them cope with the changes. The acquisition of these skills could be facilitated by attendance on a structured psycho-educational self-management programme in the company of other women at a similar stage of their treatment. Breast Cancer Care has experience of running "Moving Forward" courses, which aim to educate women about their illness and related effects, in addition to learning self-management skills. The need for reassurance and psychological support forms a key element in these courses.

Many clinicians recognise the shortfalls of current services, but are reluctant to reduce follow-up to less than 5 years. Various reasons have been given such as the re-structuring challenges required to transition to routine mammography only service for this breast cancer population including clinician resistance. Follow-up care is essentially screening (Moschetti et al., 2016), while offering the opportunity to monitor patients undergoing Tamoxifen treatment (currently 5 years), and initiate change speedily if current practice changes, and/or new endocrine therapies are recommended. Other less resource intensive approaches for monitoring would seem reasonable given the availability and acceptability of specialist nurses, information technology and telephony systems to support and manage recall for routine screening and trigger alerts to patients and general practice should recommendations regarding adjuvant hormonal therapies change.

There is no evidence of a preference for intensive or minimalist follow-up among well-informed women. Patients in trials comparing different types of follow-up tend to express satisfaction with their allocation model. Likewise, there is limited evidence regarding universal patient preference for involvement in decision-making about treatments (Collins, Bekker, & Dodwell, 2004) although studies have found that patients with increased involvement in decision-making about follow-up care reported better quality of life (Andersen, Bowen, Morea, Stein, & Baker, 2009; Andersen & Urban, 1999). Fallowfield's (2001) work in this area indicated that it is more important for patients to understand and participate in the clinician's decision-making process than to make treatment decisions themselves. This concurs with the NICE guidelines that recommend that the patient and specialist should agree a written, follow-up care plan together as part of a holistic needs assessment and care plan, and that locally agreed measures should be developed to support the woman's transition from the unit (NCSI, 2010).

Risk of recurrence is associated with the stage of disease at diagnosis. According to the All Breast Cancer Report (Cheung et al., 2009), 64% of the 28,462 invasive breast cancers diagnosed in the UK were Stage I (17%) or Stage II (47%). These groups had 5-year survival rates of 99% and 90% respectively. Follow-up practice could be stratified according to individual risk. Moreover, it would not seem unreasonable to offer women with low risk, early-stage disease alternative models of follow-up whilst reserving hospital follow-up for high-risk patients. It is within this context that a model of follow-up based on promoting a supportive, open access, self- management approach to follow-up care was developed with regard to previous work on patients' views and needs.

## 2 | METHODS

### 2.1 | Aim and design

The aim of the study was to test the acceptability of an open access supportive care model of follow-up for women with early, low-risk breast cancer, with an embedded psycho-educational self-management programme (Moving Forward). A longitudinal single-centre, open randomised controlled design was used to measure and detect trends of quality of life indicators.

### 2.2 | Sample and setting

Women newly diagnosed with AJCC Stage 1 or Stage 2 breast cancer, treated with curative intent and considered to be clinically at low risk of recurrence were invited to participate in the study. Potential participants were recruited by a breast cancer nurse following surgery and staging and where possible prior to any planned radiotherapy treatment. Women were excluded from the study if they: had Stage 3 or 4 breast cancer; were receiving or received adjuvant chemotherapy; were identified by the multidisciplinary team as requiring follow-up due to increased risk factors such as young age, had significant family history or bilateral cancers; or were taking part in breast cancer clinical trials that required follow-up as per trial protocol. Informed consent was obtained from all individual participants included in the study.

Eligible women were invited to attend a psycho-educational self-management programme designed by the UK charity Breast Cancer Care called "Living with Breast Cancer" (now known as "Moving Forward"). This comprised half-day sessions delivered over four consecutive weeks and addressed topics that included the management of breast cancer, the impact of breast cancer, breast reconstruction, lymphoedema, exercise, breast awareness after surgery, healthy eating and the management of menopausal symptoms. The programme was originally designed for breast cancer survivors with the aim of enhancing health literacy and self-confidence, supporting self-management and reducing isolation. Following attendance on the course, women were randomised into one of two groups: (1) standard hospital after-care (Control Group) and (2) open access after-care (Intervention Group). As a result of the nature of the intervention, it was not possible to blind participants to the type of after-care received.

Women in the Intervention Group were not routinely followed-up. They were provided with a resource pack designed to complement the course and details of how to access breast surgical services through a telephone helpline run by breast cancer nurses should they experience any breast cancer related concerns.

When following the open access supportive model of follow-up, patients are under the care of the consultant for the usual duration of appointment times. In this setting, it was for 5 years. During this time, if concerned or worried, a patient can return to the clinic immediately without a GP referral. Diagnostic investigations can be booked and problems resolved sooner through reducing stressful waiting times and starting further treatment, if required, with minimal delay. The open access supportive model recognises that the role of the breast cancer nurse has extended to an advanced practitioner, able to instigate investigations and complete breast examinations and biopsies. GPs are informed that their patient has attended the course and are informed how the open appointments system works. Any further communications with the patient is communicated to the GPs. The patient will have mammography annually for 5 years and receive the results through the post and their GPs will receive a copy of the report.

## 2.3 | Ethics statement

All procedures performed in this study involving human participants were in accordance with the ethical standards of the national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. The study protocol was approved by the national and local ethics and research panels. Informed consent was obtained from all individual participants included in the study.

There is no conflict of interest linked to any of the authors associated with this study. The research has been conducted to benefit the lives of breast cancer survivors, without any financial benefit to the authors.

## 2.4 | Data collection

Three Quality of Life questionnaires: EORTC Quality of Life QLQ-C30 (Aaronson et al., 1993) and EORTC QLQ-BR23 (Sprangers et al., 1996); and the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) were administered to each participant at baseline (T:0), 6 (T:1), 12 (T:2), 18 (T:3) and 24 months (T:4). The first five questions on the QLQ-BR23 questionnaire were not relevant to the current analysis and responses to these questions were not elicited from participants.

## 2.5 | Analysis

The questionnaires were scored according to the QLQ and HADS scoring manuals (Fayers, Aaronson, Bjordal, Curran, & Bottomley, 2001). The QLQ-C30 questionnaire generates scores in the following *Functional* scales: *Global health status* (QL2), *Physical functioning* (PF2), *Role functioning* (RF2), *Emotional functioning* (EF), *Cognitive functioning* (CF) and *Social functioning* (SF); and in the following *Symptom* scales: *Fatigue* (FA), *Nausea and vomiting* (NV), *Pain* (PA), *Dyspnoea* (DY), *Insomnia* (SL), *Appetite loss* (AP), *Constipation* (CO), *Diarrhoea* (DI) and *Financial difficulties* (FI). In this questionnaire, high scores of the *Functional* sub-scales represent higher levels of functioning; and low score on the *Symptom* sub-scales represent higher level of functioning.

The QLQ-BR23 questionnaire generates scores in the following *Functional* scales: *Body image* (BRBI), *Sexual functioning* (BRSEF), *Sexual enjoyment* (BRSEE) and *Future perspective* (BRFU); and in the following *Symptom* scales: *Systematic therapy side effects* (BRST), *Breast symptoms* (BRBS) and *Arm symptoms* (BRAS). The additional symptom scale of *Upset by hair loss* (BRHL) generated by the BR23 questionnaire was not considered in the current analysis, as it was based on questions in the BR23 to which responses had not been elicited. In this questionnaire, high scores of the *Functional* sub-scales represent higher levels of functioning; and low score on the *Symptom* sub-scales represent higher level of functioning.

The HADS questionnaire generated scores for the characteristics of *Anxiety* and *Depression*. In this questionnaire, low scores on both these sub-scales represent higher levels of functioning.

A small proportion of questions on all three questionnaires were left unanswered. Data imputation was undertaken following recommended methods in the questionnaire scoring manuals; hence mean values were imputed for missing values in scales in which a response was recorded from at least half of the items. Other missing values were not imputed.

Descriptive statistics (means and standard deviations) were calculated for all sub-scales considered, and sub-scale scores were inspected individually for the presence of trends.

A multilevel model formulation was utilised to indicate relationships between variables of interest to allow for variation in trends over time between different individuals. This model facilitates appropriate treatment of variables at both *patient*- and *measurement*-levels.

A total of eight series of models, both univariate and multivariate, were derived. For the HADS scale, a series of multivariate models was derived, using the scores on the *Depression* and *Anxiety* sub-scales of the HADS instrument. For the QLQ-BR23 questionnaire, a significantly lower number of responses were received on the BRSEF and BRSEE sub-scales, which could not be imputed. Inclusion of these scale scores as response variables may have compromised the accuracy of a multivariate model considering responses arising from all functional sub-scales. Hence, these sub-scales were analysed individually as a series of univariate models. The remaining functional sub-scales in the QLQ-BR23 questionnaire, BRBI and BRFU, were analysed as a series of multivariate models. The three symptom sub-scales in the BR23 questionnaire were analysed together as a further series of multivariate models.

The Global Health Status sub-scale was analysed individually as a series of univariate models. The 5 functional scales (excluding the Global Health Status sub-scale) in the QLQ-C30 questionnaire were analysed together as a series of multivariate models. The nine symptom scales in the QLQ-C30 questionnaire were analysed together as a further series of multivariate models.

## 2.6 | Model selection strategy

For each set of outcome measures considered, a total of 5 nested models were derived: a null model including only the constant term and no explanatory variables; a model additionally including the age covariate; a model additionally including the grouping factor; a model including both variables and a model including both variables and the interaction between them.

For each model, the deviance (likelihood ratio statistic) was determined. A statistically significant reduction in deviance between two nested models with degrees of freedom $\nu_1$ and $\nu_2$, which has an approximate $\chi^2$ distribution on $\nu_1$–$\nu_2$ degrees of freedom, was taken to be indicative of a parameter which should remain in the model. In this way likelihood ratio considerations determined which of the five models associated with each set of responses measures provided the best summary of the data.

All analyses were performed using the MLwiN software Version 2.25, using the Iterated Generalised Least Squares (IGLS) procedure for parameter estimation.

## 3 | RESULTS

### 3.1 | Descriptive summary of data

One hundred and twelve women aged 29.6–85.9 years at baseline (T:0) recovering from breast cancer were recruited to the study. Fifty-six participants were randomised to the control group and 56 to the intervention group. One participant failed to complete baseline data after recruitment. A further 29 individuals were lost to follow-up between baseline and 24 months; hence, a full set of follow-up data was received from 82 patients (73%).

The mean age of patients in the control group at baseline was 60.5 years (*SD* = 9.79 years); the mean age of patients in the intervention group at baseline was 60.7 years (*SD* = 10.86 years). Means and standard deviations of transformed scores obtained on all sub-scales of all three questionnaires at baseline and 6, 12, 18 and 24 months are given in Tables 1–3 below.

No obvious time-dependent trends were observed in either of the HADS sub-scales. Scores recorded in the control group were slightly higher on the *Depression* sub-scale than those recorded in the intervention group at most time-points, indicating higher functionality in the intervention group with respect to depression. However, scores recorded in the control group were slightly lower on the *Anxiety* sub-scale than those recorded in the intervention group at all time-points, indicating higher functionality in the control group with respect to anxiety. In both cases, the relative month-by-month change, and the difference between groups, was small compared with within-patient variability.

Variability remained approximately constant in both scales across the 24-month period. Considering the 24-month period as a whole, functionality declines slightly in both sub-scales, in both control and intervention groups.

No obvious time-dependent trends were observed in any of the QLQ-BR23 sub-scales, with the exception of the BRBS sub-scale, in which a monotonic downward trend (corresponding to continuously improving functioning) was shown in both the control and intervention groups. Other groups appeared approximately static, with the BRSEE scale scores in the control group being completely static. However, in the intervention group this sub-scale showed a fall of 16.7 percentage points over 24 months.

Variability remained approximately constant in all scales across the 24-month period. Considering the 24-month period as a whole, improved functionality compared with baseline values was recorded in approximately half of the functional and symptom sub-scales considered, in both control and intervention groups.

No obvious time-dependent trends were observed in any of the QLQ-C30 sub-scales. Some sub-scales, such as the DY, AP and CO sub-scales exhibited a degree of oscillation in either or both groups. Other sub-scales appeared to be fairly static over time, with only the FI sub-scale in the intervention group behaving monotonically. However, the existence of one monotonic sub-scale in a data set of this size would be expected even under the hypothesis of no time-dependent trends.

Variability remained approximately constant in all scales across the 24-month period. Considering the 24-month period as a whole, improved functionality compared with baseline values was recorded in just over half of the functional and symptom sub-scales considered, in both control and intervention groups.

### 3.2 | Model selection

Changes in likelihood ratio statistics, plus the assessment of significance of the change in these statistics between models, indicated that a model which best describes the Depression and Anxiety sub-scales of the HADS questionnaire; the BRBI, BRFU, BRSEF, BRST, BRBS and BRAS sub-scales of the QLQ-BR23 questionnaire; and PF2, RF2, EF, CF and SF sub-scales of the QLQ-C30 questionnaire, would include an age factor but not a grouping factor. Such a model cast in a multilevel context is given by the expression

$$y_{jk} = \beta_{0jk} + \beta_1 x_{1jk}$$

where $y_{jk}$ is the score obtained by the $k^{th}$ patient on the $j^{th}$ measurement occasion; $\beta_{0jk}$ is a constant including random terms at the *patient* and *measurement*-levels; and $x_{1jk}$ is the age of the $k^{th}$ patient at the $j^{th}$ measurement occasion.

Neither age nor group were found to significantly improve goodness-of-fit in a model which best describes the BRSEE sub-scale of the QLQ-BR23 questionnaire; and the G1 sub-scale of the QLQ-C30 questionnaire. Such a model cast in a multilevel context is given by the expression

$$y_{jk} = \beta_{0jk}$$

where $y_{jk}$ and $\beta_{0jk}$ are defined as above.

Both age and group, plus the interaction between them, were found to significantly improve goodness-of-fit in a model which best describes the FA, NV, PA, DY, SL, AP, CO, DI and FI sub-scales of the

**TABLE 1** HADS questionnaire sub-scale scores (mean [*SD*]): control and intervention groups

| | Control group | | | | | Intervention group | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sub-scale | Baseline | 6 months | 12 months | 18 months | 24 months | Baseline | 6 months | 12 months | 18 months | 24 months |
| Depression[a] | 3.53 (3.45) | 3.58 (3.70) | 3.59 (4.03) | 3.46 (3.18) | 3.94 (4.12) | 3.19 (2.72) | 2.99 (2.89) | 3.44 (3.09) | 3.73 (3.39) | 3.71 (3.24) |
| Anxiety[a] | 5.71 (4.43) | 5.53 (4.12) | 5.47 (4.80) | 5.83 (4.52) | 5.74 (5.00) | 6.59 (3.42) | 6.39 (4.05) | 6.32 (3.72) | 7.01 (4.21) | 7.00 (4.60) |

[a]A low score on this sub-scale represents a higher level of functioning.

**TABLE 2** QLQ-BR23 questionnaire sub-scale scores (mean [*SD*]): control and intervention groups

| | Control group | | | | | Intervention group | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sub-scale | Baseline | 6 months | 12 months | 18 months | 24 months | Baseline | 6 months | 12 months | 18 months | 24 months |
| BRBI[a] | 75.7 (28.6) | 73.8 (31.2) | 77.0 (30.3) | 79.0 (27.2) | 80.4 (26.2) | 78.7 (21.1) | 82.0 (16.7) | 80.5 (20.9) | 82.0 (20.3) | 79.4 (25.9) |
| BRSEF[a] | 27.6 (29.0) | 23.0 (23.3) | 20.7 (24.7) | 20.1 (22.0) | 18.4 (23.7) | 28.0 (26.2) | 33.3 (28.5) | 24.7 (28.9) | 24.7 (28.9) | 24.7 (25.0) |
| BRSEE[a] | 72.7 (25.0) | 72.7 (25.0) | 72.7 (29.1) | 72.7 (32.7) | 72.7 (32.7) | 77.8 (27.2) | 83.3 (18.3) | 77.8 (27.2) | 66.7 (21.1) | 61.1 (25.1) |
| BRFU[a] | 65.7 (30.3) | 57.4 (30.5) | 59.3 (28.9) | 62.0 (26.6) | 58.3 (31.2) | 61.5 (24.1) | 55.2 (26.2) | 57.3 (28.4) | 60.4 (29.9) | 55.2 (30.1) |
| BRST[b] | 28.9 (21.1) | 29.6 (23.5) | 27.5 (24.6) | 25.0 (21.5) | 25.5 (22.4) | 26.0 (22.1) | 22.6 (16.8) | 22.4 (18.7) | 25.0 (22.2) | 26.4 (20.7) |
| BRBS[b] | 20.9 (18.3) | 16.8 (18.9) | 15.5 (22.5) | 13.4 (16.8) | 9.3 (11.2) | 23.2 (20.2) | 17.2 (14.6) | 15.4 (18.1) | 12.6 (13.7) | 11.5 (12.8) |
| BRAS[b] | 13.3 (18.2) | 15.4 (22.7) | 14.5 (23.6) | 11.1 (16.1) | 15.4 (20.8) | 14.5 (14.3) | 11.8 (15.9) | 12.1 (15.3) | 10.8 (15.3) | 12.0 (15.0) |

BRAS, Arm symptoms; BRBI, Body image; BRBS, Breast symptoms; BRFU, Future perspective; BRSEE, Sexual enjoyment; BRSEF, Sexual functioning; BRST, Systematic therapy side effects.
[a]A high score on this sub-scale represents a higher level of functioning.
[b]A low score on this sub-scale represents a higher level of functioning.

**TABLE 3** QLQ-C30 questionnaire sub-scale scores (mean [*SD*]): control and intervention groups

| | Control group | | | | | Intervention group | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Sub-scale | Baseline | 6 months | 12 months | 18 months | 24 months | Baseline | 6 months | 12 months | 18 months | 24 months |
| QL2[a] | 72.9 (18.8) | 71.4 (22.4) | 75.0 (20.3) | 71.4 (24.8) | 75.0 (19.8) | 70.7 (18.1) | 74.2 (16.7) | 69.4 (21.5) | 70.7 (24.0) | 69.9 (20.5) |
| PF2[a] | 86.1 (14.0) | 85.4 (17.1) | 87.2 (13.0) | 86.3 (14.7) | 86.1 (15.3) | 86.5 (17.5) | 86.5 (17.0) | 84.7 (17.9) | 85.7 (20.7) | 86.7 (19.3) |
| RF2[a] | 78.2 (27.6) | 82.4 (29.3) | 83.8 (23.4) | 81.5 (28.7) | 85.6 (23.6) | 75.6 (25.8) | 88.9 (16.0) | 79.4 (21.3) | 83.9 (25.3) | 82.2 (22.7) |
| EF[a] | 77.9 (17.7) | 78.8 (24.2) | 78.3 (25.6) | 78.8 (22.5) | 75.4 (27.4) | 75.8 (17.9) | 76.1 (20.4) | 77.5 (24.4) | 75.5 (22.4) | 75.3 (24.8) |
| CF[a] | 79.5 (24.9) | 76.5 (28.5) | 79.1 (27.0) | 80.3 (20.9) | 80.3 (24.4) | 78.5 (20.3) | 79.6 (20.1) | 76.9 (19.6) | 78.0 (17.9) | 76.9 (21.4) |
| SF[a] | 82.9 (22.5) | 84.6 (23.4) | 85.0 (22.6) | 87.6 (20.1) | 85.5 (21.7) | 79.6 (23.8) | 90.9 (14.8) | 86.6 (21.3) | 88.7 (20.8) | 86.6 (20.8) |
| FA[b] | 30.9 (26.9) | 32.1 (26.8) | 29.3 (30.1) | 28.7 (29.4) | 30.2 (26.9) | 33.0 (17.2) | 26.4 (18.9) | 25.7 (23.4) | 27.2 (24.9) | 27.2 (24.6) |
| NV[b] | 3.8 (8.1) | 6.4 (14.1) | 2.6 (8.1) | 7.7 (18.3) | 5.6 (12.9) | 4.4 (8.9) | 3.3. (9.2) | 5.0 (9.9) | 8.9 (15.0) | 7.8 (16.2) |
| PA[b] | 18.8 (28.1) | 20.1 (25.1) | 20.1 (29.4) | 23.1 (28.5) | 17.9 (27.4) | 22.7 (21.6) | 18.2 (16.3) | 20.2 (25.3) | 19.7 (23.0) | 15.7 (20.8) |
| DY[b] | 16.7 (27.0) | 19.4 (30.2) | 9.3 (17.1) | 11.1 (23.9) | 14.8 (24.5) | 12.6 (20.7) | 14.9 (24.5) | 14.9 (22.9) | 19.5 (26.0) | 14.9 (26.1) |
| SL[b] | 34.3 (33.3) | 32.4 (33.3) | 34.3 (34.3) | 36.1 (33.2) | 35.2 (32.8) | 34.5 (31.5) | 27.6 (25.3) | 33.3 (28.2) | 33.3 (28.2) | 32.2 (28.8) |
| AP[b] | 9.9 (17.3) | 5.4 (12.5) | 6.3 (13.3) | 8.1 (19.9) | 7.2 (13.9) | 6.7 (16.1) | 10.0 (21.7) | 7.8 (18.9) | 11.1 (22.0) | 5.6 (19.7) |
| CO[b] | 14.5 (26.3) | 8.5 (23.8) | 9.4 (25.3) | 11.1 (27.9) | 12.8 (26.1) | 17.2 (26.2) | 9.2 (17.6) | 14.9 (26.1) | 23.0 (33.5) | 18.4 (30.3) |
| DI[b] | 7.2 (16.0) | 8.1 (16.5) | 9.9 (22.0) | 7.2 (13.9) | 10.8 (19.3) | 6.7 (16.1) | 8.9 (15.0) | 7.8 (18.9) | 4.4 (11.5) | 6.7 (16.1) |
| FI[b] | 10.3 (25.5) | 12.0 (25.9) | 7.7 (23.5) | 11.1 (25.7) | 10.3 (27.7) | 13.8 (26.0) | 9.2 (26.6) | 6.9 (22.5) | 6.9 (22.5) | 5.7 (21.9) |

AP, Appetite loss; CF, Cognitive functioning; CO, Constipation; DI, Diarrhoea; DY, Dyspnoea; EF, Emotional functioning; FA, Fatigue; FI, Financial difficulties; NV, Nausea and vomiting; PA, Pain; PH2, Physical functioning; RF2, Role functioning; SF, Social functioning; SL, Insomnia; QL2, Global health status.
[a]A high score on this sub-scale represents a higher level of functioning.
[b]A low score on this sub-scale represents a higher level of functioning.

QLQ-C30 questionnaire. Such a model cast in a multilevel context is given by the expression

$$y_{jk} = \beta_{0jk} + \beta_1 x_{1jk} + \beta_2 x_{2k} + \beta_{12} x_{1jk} x_{2k}$$

where $y_{jk}$, $\beta_{0jk}$, $x_{1jk}$ are defined as above; $x_{2jk}$ is the group of the $k^{th}$ patient at the $j^{th}$ measurement occasion (*patient*-level variable); and $x_{1jkx2k}$ is the age group interaction.

Age appears in 22 models and aftercare group in nine models. Significance levels of 0.00233 for age; and 0.00568 for group corresponded to familywise error rates of 5% in both cases. Under these criteria, age is statistically significant with respect to the BRSEF, BRFU and BRST sub-scales of the QLQ-BR23 questionnaire; and the PF2 sub-scale of the QLQ-C30 questionnaire. At best estimate, an increase in age of 1 year is associated with: a reduction of 1.01 points on the BRSEF sub-scale; an increase of 0.66 points on the BRFU sub-scale; a reduction of 0.68 points on the BRST sub-scale and a reduction of 0.42 points on the PF2 sub-scale.

The aftercare group as a main effect was not statistically significant with respect to any sub-scale in which the age·group interaction was not included in the final model. The age·group interaction was

statistically significant with respect to the DI sub-scale of the QLQ-C30 questionnaire.

For all outcome measures except the NV and DI sub-scales of the QLQ-C30 questionnaire, the majority of model variance calculated using the variance partition coefficient occurred at the patient level, with relatively low variation in scores obtained from the same patient on different measurement occasions. These sub-scales were both associated with very low scores, indicating high functionality. However, there is a factor of at least two separating the mean scores on these sub-scales recorded at different months.

## 4 | DISCUSSION

In general, the scores recorded in both groups (Tables 1–3) indicated a study population who were generally in good health. Even at baseline, at which point it might be expected scores to be at a low point, all the functional scales on the C30 questionnaire, plus the BRBI, BRSEE and BRFU functional scales on the BR23, were all scored at 65% or above. All symptom scores were below 25% at baseline and the scores on some sub-scales (DI, AP, NV) were below 10%. Baseline depression rates were quite low (mean score of 3.6 of 14), but baseline anxiety levels had a mean score of 6.4 out of 14. No significant improvement over 2 years from the baseline measurement was recorded in most scales (Tables 1–3).

A descriptive assessment of the performance of the intervention group versus the control group did not necessarily imply that each scale is of equal merit, which may not be the case. For example, it may be more important to show better improvement on, say, global health than on a scale such as appetite loss.

A clear finding of the results was that very few time-dependent trends were observed. Quality of life scores did not change significantly over the 24-month follow-up period. The sole time-dependent trend, exhibited in both groups by the *Breast Symptoms* sub-scale (Table 1) was not unexpected, considering that the sample comprised patients recovering from breast cancer. Furthermore, such an event was not statistically unlikely: for 24 such sequences in each of two groups, the probability of two or more monotonic sequences is 0.191 under a null hypothesis of no time-related component.

A notable strength of this longitudinal study was the high retention rate, with 82 of 112 patients (73%) followed-up for the full 2-year study period. However, those in better health may have been more likely to be lost to follow-up at an early stage, possibly because they wished to forget about their experience of cancer and move on with their lives. A comparison of responses from patients who were subsequently lost to follow-up and those who remained on the study until the end of the follow-up period did not reveal any obvious systematic differences in responses on any sub-scale.

In general, the majority of responses received were valid, and little imputation was required. The response rate of questions on the BRSEF and BRSEE sub-scales was lower than on other questions, possibly being due to the perception that these questions were eliciting private information or information irrelevant to the monitoring of recovery from breast cancer. A small number of respondents provided unsolicited comments on these sections of their questionnaires to that effect.

One limitation of the study was that demographic, social and comorbidity factors were not recorded on the participants, other than age; although effective randomisation of a sample size of 112 should remove or reduce the potential for imbalances across groups. However, some unsolicited comments provided by respondents on their questionnaires suggested a belief that their responses were due wholly or partly to causes other than breast cancer. For example, a patient in her 80 s reported fatigue, making an association with her age. Another patient noted that she was an arthritis sufferer and the progress of this ailment was affecting her well-being to a greater extent than the previous episode of breast cancer. Another participant recorded low overall quality life scores and noted that she had recently suffered a family bereavement. It is accepted that the internal validity of this study may have been limited by the presence of such generally unrecorded factors.

Patient age has been found to be a far more important predictor of sub-scale scores than the assigned aftercare group. Age appeared as a main effect or as part of an interaction in all models with the exception of models using the GF1 and BRSEE outcome measures. The significant interaction on the DI sub-scale implies that the effect of aftercare group was different for patients of different ages. Among younger patients, those in the control group had higher functionality, whereas among older patients, those in the intervention group had higher functionality.

There is no evidence that people who have had early breast cancer are disadvantaged by the open access, supportive care model in terms of quality of life experienced by patients using a variety of quality of life indicators. The innovative model for follow-up was evaluated and demonstrated as a feasible alternative to hospital-based follow-up, which has the added advantage of not having to attend a clinic that may reinforce unnecessary worry of recurrence by low-risk patients. The pressures in the clinics today are enormous and continue to increase with all new patient referrals. People who have secondary disease are living longer due to improved treatments and require regular clinic appointments, which add to the demand. The open access supportive care model may be viewed as radical in some circles; however, this study presents a reasonable case for implementing this approach. The results from the pilot study confirmed that this was a robust programme of education, fulfilling patients' needs at this point and in the future. Evaluation confirmed that the women were confident with their own knowledge and understanding of diagnosis and treatments and the potential risks to themselves. They needed to be confident of self-care, assessment of themselves and in knowing which health care professional should be contacted. Furthermore, the clinicians fully supported the course as an acceptable substitute to clinic attendance recognising that they cannot provide the same level of support and education in a brief clinic visit.

## 5 | CONCLUSION

Our innovative open access model for follow-up was evaluated and demonstrated to be a feasible and acceptable alternative to

routinised hospital-based follow-up; it is now embedded in practice in the UK through the charity Breast Cancer Care. Our work adds to the evidence for stratified follow-up for low-risk cancer patients, which includes open access to breast care nurses and patient self-management education for patients. Patient initiated access to care removed the necessity to attend a hospital-based clinic potentially increasing NHS efficiencies and reducing patient's unnecessary anxiety about recurrence and facilitating better recovery. Stratified follow-up pathways based person-centred approaches and holistic supportive and wellness care models now form part of the NHS cancer strategy (NCSI, 2013; NICE, 2002) and can be viewed as a safe, preferable way forward.

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