



Cancer survivors' experiences of a community-based cancer-specific exercise programme: results of an exploratory survey

Susan Catt¹ · J. Sheward² · E. Sheward² · H. Harder¹

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Abstract

Purpose Exercise levels often decline following cancer diagnosis despite growing evidence of its benefits. Treatment side effects, older age, lack of confidence and opportunity to exercise with others in similar circumstances influence this. Our study explored the experiences of people attending a cancer-specific community-based exercise programme (CU Fitter™).

Methods A survey distributed to those attending the programme gathered demographic/clinical information, self-reported exercise levels, information provision and barriers to/benefits of exercise.

Results Sixty surveys were evaluable from 65/100 returned (62% female, 68% > 60 years, 66% breast/prostate cancer). Most (68%) were receiving treatment. Sixty-eight percent attended classes once or twice weekly. Fifty-five percent received exercise advice after diagnosis, usually from their hospital doctor/nurse. More (73%) had read about exercising, but less used the Internet to source information (32%). Self-reported exercise levels were higher currently than before diagnosis ($p = 0.05$). Forty-eight percent said their primary barrier to exercising was the physical impact of cancer/treatment. Improving fitness/health (40%) and social support (16%) were the most important gains from the programme. Many (67%) had made other lifestyle changes and intended to keep (50%) or increase (30%) exercising.

Conclusions This community-based cancer-specific exercise approach engaged people with cancer and showed physical, psychological, and social benefits.

Implications for cancer survivors Community-grown exercise initiatives bring cancer survivors together creating their own supportive environment. Combining this with instructors familiar with the population and providing an open-ended service may prove particularly motivating and beneficial. Further work is required to provide evidence for this.

Keywords Cancer · Exercise · Health behaviour · Physical activity · Quality of life · Survivorship

Introduction

A predicted > 3% annual rise of cancer survivors in the UK could mean that there will be over five million, mostly older

people, by 2040 [1]. However, many people treated for cancer experience ongoing poor health and mental well-being and reduced quality of life (QoL) [2]. Exercise or physical activity (PA) is proven to be beneficial for those with cancer, and increasing evidence shows that it can be safely performed during and after treatment, provided that individual limitations are considered and monitored [3]. PA can preserve or improve physical function and psychological well-being, decrease the impact of treatment side effects, reduce the risk of recurrence, and increase survival [4].

The UK Chief Medical Officers have published general PA guidelines for adults [5]. Recommending at least 150 min of moderate intensity exercise (e.g. fast walking) per week performed in bouts of 10 min or longer. Muscle strengthening activity (e.g. exercising with weights, carrying heavy shopping) should be undertaken 2–3 times a week, and time spent sedentary minimised. No cancer-specific PA guidelines exist, but consensus is that the general guidelines are applicable for

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✉ Susan Catt
S.L.Catt@sussex.ac.uk

¹ Sussex Health Outcomes Research and Education in Cancer (SHORE-C), Brighton and Sussex Medical School, University of Sussex, Falmer, Brighton BN1 9RX, UK

² Cancer United™ (charity No. 1155747), Millfield House, Station Road, Angmering, West Sussex BN16 4HY, UK

adult cancer survivors [6]. Nevertheless, few cancer patients actually comply with these recommendations [7]. PA levels are reported to drop after a cancer diagnosis [8], and influencing factors include the following: older age, previous comorbidities, cancer stage and treatment side effects [9–13]. Lack of confidence or knowledge regarding appropriate exercise levels and limited access to targeted programmes and/or facilities where patients can exercise with others in the same situation are also common barriers [11, 14]. To help cancer patients address these obstacles, referral-based exercise schemes have been introduced throughout the UK. Most are organised in partnership with the NHS, Clinical Commissioning Groups or Macmillan cancer support and offer supervised exercise programmes tailored for individuals or groups, during or after cancer treatment. Participation is usually free but duration of the programme is often predetermined and time-limited.

A recent study showed that enrolment in a fee-for-service cancer-specific exercise programme (including paying for the initial fitness assessment) positively affected QoL in cancer survivors, increased self-reported exercise and reduced perceived barriers to PA [15]. Cancer United™ (a registered cancer support charity based in West Sussex, UK) developed a fee-for-service cancer-specific exercise programme (CU Fitter™) from cancer diagnosis onwards with no limit to duration of participation. This community-based programme was started by a cancer survivor (JS) and runs in a dedicated exercise facility. It offers outreach through ‘pop-up gyms’ in two other locations and also provides exercise sessions (twice weekly) in local support group meetings. Classes are delivered by qualified personal trainers with additional education in cancer-specific exercise. Before a safe and tailored exercise programme is drawn-up physical and psychological health, individual needs and applicable motivational techniques are assessed. Regular review is integral to each exercise plan. One-to-one single sessions and a range of different group exercise classes are available, ranging from low-impact exercise, strength, flexibility and balance training, to classes to improve upper-body mobility or muscle and bone density. Some classes cater for specific cancer groups (i.e. breast or prostate), or treatment stage (e.g. during chemotherapy) or for those preparing to return to mainstream facilities. This pilot study aimed to explore the experiences of people with cancer who attend this tailored community-based exercise programme from diagnosis onwards as preliminary work for future comparative longitudinal research with exercise interventions.

Methods

Survey sample and procedures

A non-experimental design was employed. A convenience sample of people participating in CU Fitter™ classes was

invited to complete an anonymous paper survey about their past and present exercise habits and experiences. The survey was conducted July to October 2016. Brighton and Sussex Medical School (BSMS) Research Governance and Ethics Committee (Ref No: 16/024/HAR) granted ethical approval for the study.

The survey was informed by a scoping review of the literature, input from patients with experience of returning to PA after cancer and exercise trainers working with this population. A draft was piloted with a small number of CU Fitter™ members (not included in the study sample) and refinements made from their feedback. The survey comprised multiple-choice and open-ended questions divided into four sections covering the following: (1) demographic and clinical characteristics, (2) PA and exercise habits before the cancer diagnosis, (3) PA and exercise experiences (including barriers and facilitators) since attending the exercise programme and (4) future life style intentions.

The Godin-Shephard Leisure-Time Physical Activity Questionnaire (GSLTPAQ) was embedded within the survey to measure self-reported leisure-time PA [16, 17]. Respondents reported PA levels for two time-frames (i.e. pre-diagnosis and current PA levels) by indicating how many times a week they had been exercising for at least 15 min. PA is categorised as mild (minimal effort), moderate (not exhausting) and strenuous (heart beats rapidly) with examples provided. The number in each category is multiplied by 3, 5 and 9 respectively, and the results summed into a total weekly leisure activity score, the Leisure Score Index (LSI). The scores obtained from moderate and strenuous PA can be used to classify respondents into active (moderate-to-strenuous $LSI \geq 24$) and insufficiently active (moderate-to-strenuous $LSI < 24$) categories according to published PA guidelines for public health [5] and cancer survivors [6].

Survey analysis

Survey responses to open-ended questions were coded and summary statistics generated for all data: counts, percentages and means where appropriate. A paired sample *t* test was used to compare past and current self-reported PA levels derived from the LSI values on the GSLTPAQ ($p \leq .05$).

Results

Sample characteristics

One hundred questionnaires were distributed and 65 returned. Of these, 60 were evaluable and 5 were excluded as they had been completed by partners of those with cancer.

Table 1 shows the demographic and clinical characteristics. Respondents were predominantly older (41; 68% > 60 years), female (37; 62%) and most commonly diagnosed with breast

Table 1 Demographic and clinical characteristics of survey respondents

Characteristics	N (%)
Age	
≤ 40 years	1 (2)
41–60 years	18 (30)
61–70 years	24 (40)
71–80 years	11 (18)
> 80 years	6 (10)
Sex	
Female	37 (62)
University education	
Yes	19 (32)
Employed	
Yes	9 (15)
Partnered	
Yes	37 (62)
Cancer diagnosis	
Breast	26 (43)
Prostate	14 (23)
Haematological	9 (15)
Lung	4 (7)
Colorectal	3 (5)
Renal	2 (3)
Head and neck	1 (2)
Bladder	1 (2)
Previously received cancer treatment^a	
Yes	55 (92)
Surgery	13 (22)
Chemotherapy	32 (53)
Radiotherapy	37 (62)
Hormone therapy	28 (47)
Current cancer treatment^a	
Yes	41 (68)
Chemotherapy	6 (10)
Radiotherapy	2 (3)
Hormone therapy	29 (48)
Bone strengthening medication	7 (12)
Analgesia	6 (10)
Other ^b	3 (5)
Comorbidities^a	
Yes	37 (62)
Diabetes	5 (8)
Heart disease/stroke	1 (2)
Asthma	3 (5)
Hypertension	15 (25)
Arthritis	6 (10)
Osteoporosis	2 (3)
Depression/anxiety	4 (7)

^a Multiple response options possible (percentages may not add up to 100%)

^b Targeted therapy or immunotherapy

(26; 43%) or prostate (14; 23%) cancer. Nearly a quarter had undergone surgery and larger proportion radiotherapy (37; 62%), chemotherapy (32; 53%) and/or hormone therapy (28; 47%). The majority (41; 68%) were still receiving active cancer treatment, mostly hormone therapy (29; 48%). Comorbidity was common (37; 62%), particularly hypertension (15; 25%) and arthritis (6; 10%).

Knowledge of PA guidelines and information provision

Approximately half (31; 52%) were aware of the UK Department of Health recommendations for adult levels of exercise. Just over half (33; 55%) had received verbal advice about exercising after the cancer diagnosis, usually from their hospital doctor (14; 23%) or nurse (19; 32%). Seven (12%) were informed by a primary care practitioner. The majority (44; 73%) had read about exercising after a cancer diagnosis, mostly in a Macmillan booklet (19; 32%), a Cancer Research UK leaflet (15; 25%), hospital's own leaflet (10; 17%) or the Breast Cancer Care leaflet (11; 18%). Fewer (19; 32%) had sourced information from a website, usually the Macmillan and/or Cancer Research UK websites (both 7; 12%), or Breast Cancer Care (6; 10%).

Exercise referral and programme usage

Twenty-three respondents (38%) were referred to the exercise programme by a healthcare professional (HCP). Others had seen an advert in a local paper or local news coverage on television (12; 20%) or were informed by a friend (9; 15%), through a (cancer) support group (6; 10%) or other exercise group (5; 8%). Most (45; 75%) lived within 5 miles of a location where the programme was held. Main reasons for joining were as follows: to improve fitness, mobility or flexibility (25; 42%), to get personalised support from a cancer exercise specialist (13; 22%), to exercise with like-minded people (11; 18%) or to get help with the physical (6; 10%) or emotional (6; 10%) recovery after cancer. Table 2 shows the reported differences between using CU Fitter™ and mainstream exercise services; sharing the same cancer experiences was mentioned by 42%.

Most respondents were recent members (41; 68% ≤ 6 months), commonly attending sessions once or twice per week (27; 45% and 22; 37%, respectively). They attended various exercise classes including sessions for people with prostate (14; 23%) or breast cancer (13; 22%), chemotherapy-specific sessions (16; 27%) and classes aimed at the final stages of cancer recovery (8; 13%). Six (10%) had one-to-one single sessions. In addition to the programme, most were keeping active by gardening (43; 73%) and walking or hiking (31; 52%). Cycling and swimming (both 11; 18%), yoga (11; 18%) and resistance (weight) training (10; 17%) were also

Table 2 Reported enhancements of the cancer-specific programme over mainstream exercise facilities

Nominated enhancements ^a	N (%)
Sharing same experience (i.e. cancer)	25 (42)
Fun and safe exercise environment	16 (27)
Exercise tailored to cancer and treatment	14 (23)
Small groups	12 (20)
Knowledgeable trainers	10 (17)
Other	8 (13)

Other: absence of competition, aimed at improving well-being, lower costs

^a Multiple response options possible

common. Over half (48; 62%) did between two and four of these additional PA activities per week; only four (7%) reported doing no other activities.

Self-assessed levels of PA

Table 3 summarises the PA levels reported on the GSLTPAQ. More were classified as active (i.e. moderate-to-strenuous LSI ≥ 24) currently than before diagnosis (37 versus 26%). The number who currently reported they never exercised regularly was half that of those who reported this pre-diagnosis (6; 11% versus 12; 22%, respectively). A paired sample *t* test for the LSI indicated a significant increase in current PA levels (28.0, SD 21.7) compared to pre-diagnosis levels in the sample (23.1, SD 18.9); *t* (53) = -1.984, *p* = 0.05). Pre-diagnosis and currently, eight (15%) were categorised as being active and 12 (22%) were inactive in the past but currently active. Whereas 28 (52%) were inactive for both of these time-frames. Six (11%) were currently inactive having been active pre-diagnosis; of these four were on pain medication and one was receiving palliative chemotherapy.

Perceived barriers and facilitators to exercise

A range of barriers and facilitators to PA were commonly endorsed from a predefined list presented in the survey (see additional data in Online Resource 1). From the predefined list, only 11 (18%) chose no barriers. Half (30; 50%) indicated having to overcome feeling too unwell, tired or in pain to exercise. Also not knowing how to start or what kind of exercise to do was a common hurdle (27; 45%), as was a fear of causing physical damage to themselves (20; 33%). Respondents were also asked to identify their single, main barrier and benefit to exercising in a free-text response, see Table 4 which includes verbatim quotations. From this, the main barrier for half (29; 48%) was physical:

the physical effects of cancer and/or treatment, being unfit or immobile.

Respondents endorsed multiple benefits of exercising. Most agreed PA supported them in getting back to or improving their fitness levels (49; 82%), or generally improving their health (42; 70%). Having fun and meeting/socialising with others were also important (respectively, 47; 78% and 46; 77%). In free-text report, the main benefits from exercise were found to be improving health and fitness (23; 40%) and gaining social support (10; 16%).

Future intentions to exercise

Many had goals to keep exercising (30; 50%) or increase their levels (18; 30%). Nine (15%) said that they would like to resume previous exercise activities. Large proportions were either very (31; 52%) or quite (23; 38%) confident in their ability to continue to exercise/stay physically active. A majority (40; 67%) reported having adopted other lifestyle changes, most commonly healthier eating (30; 50%), reduction in alcohol intake (12; 20%) or using stress reducing techniques, e.g. meditation or mindfulness (14; 23%).

Experience with technology

A quarter already used exercise technology (e.g. pedometer, smartwatch or fitness apps), and most using these items said they were 'very/quite' helpful (11; 73%). Of the remaining three quarters not currently using technology over half (23; 51%) were interested in exploring if it could be useful for them.

Table 3 Self-reported PA levels from the GSLTPAQ

	Pre-diagnosis	Post-diagnosis
Frequency of regular exercise per week ^a : <i>n</i> (%)		
Often	12 (22)	15 (27)
Sometimes	31 (56)	34 (62)
Never	12 (22)	6 (11)
Total Leisure Score Index ^b		
Mean (SD)	23.1 (18.9)	28.0 (21.7)
Range (min-max)	0–101	0–109
Active classification ^{b,c} : <i>n</i> (%)	14 (26)	20 (37)

PA activity, *GSLTPAQ* Godin-Shephard Leisure-Time Physical Activity Questionnaire

^a Five responses missing due to incomplete data

^b Six responses missing due to incomplete data

^c Active classification is a moderate-to-strenuous total Leisure Score Index ≥ 24

Table 4 Main perceived barriers and benefits to physical activity after a cancer diagnosis

Main barrier to exercise ^a	N (%)	Illustrative quotes
Physical effects of cancer and/or treatment	21 (35)	‘[I had] joint and muscle pain as side effect of hormone therapy’ (F, age 61–70); ‘Chemo has affected my feet, and balance is a problem (M, age 51–60)
Being unfit	6 (10)	‘[My] energy levels were low’ (F, age 71–80); ‘[My] loss of core strength’ (F, age 61–70)
Lack of knowledge and/or confidence	6 (10)	‘[I was] worried it wasn’t safe’ (F, age 41–50); ‘[Not knowing] how much I could do [and was] able to do’ (F, age 51–60)
Lack of time or motivation	5 (8)	‘The challenge was [...] finding time and energy once I started work again’ (F, age 31–40); ‘[It was difficult] fitting sessions into very busy week’ (M, age 61–70)
Mobility problems	2 (3)	‘I was immobile for so many months and required a carer’ (F, age 51–60)
Other	3 (5)	‘Finding classes locally that are reasonably priced’ (F, age 61–70); ‘Not having anyone to exercise with’ (M, age 61–70)
<i>No barriers to exercise</i>	6 (10)	–
Main benefit from exercise^b		
Improving health and fitness	25 (42)	‘Regaining my former strength’ (M, age > 80); Getting back to what I was like before diagnosis, and having confidence to go back to mainstream exercise classes (F, age 41–50)
Getting support from other cancer patients	10 (17)	‘Help, comfort, understanding. After my first session I felt I was becoming alive again’ (F, 71–80); ‘[There is] lots of support and encouragement. [It’s] being with people who understand how you feel (F, age 41–50)
Improving well-being and mood	6 (10)	‘Improved confidence and positive mental attitude’ (F, age 41–50); ‘[It’s] helping me get my life back, will not let cancer beat me’ (F, age 51–60); ‘Feeling in control of my life [again]’ (F, age 51–60)
Having fun	6 (10)	‘[I get] a feeling of wellbeing and we have a good laugh as the classes are great fun’ (F, age 71–80); ‘The feeling you’re not alone and have a laugh at the banter which goes on’ (M, age 51–60)
Tailored activities	4 (7)	‘[There is] a professional encouraging instructor in good surroundings’ (M, age 61–70); ‘[It’s] a place for people to exercise with trainers who understand the issues you have’ (F, age 61–70)

^a 49/60 specified main barrier to participating in PA

^b 51/60 specified main benefit from participation

Discussion

Recent evidence confirms that PA can have positive effects for cancer survivors both in terms of physical and psychological health and overall QoL [18, 19]. An association has been found between PA and survival; there is also documentation that PA reduces or prevents some of the adverse effects of cancer and its treatment [4, 20]. The current one-off survey summarises the exercise experiences of a group of cancer survivors. To regain confidence and fitness, they had enrolled in a community-based cancer-specific exercise programme developed by a fellow cancer survivor. The group is characteristically similar to the population of people living with cancer in the UK; most were older people with one of the more common cancer diagnoses. The results reflected that the exercise programme was a new venture for the majority of respondents as most joined within the last 6 months.

It is known that the general population in the UK has poor knowledge of the recommendations regarding exercising to stay healthy, just 18% being aware of this information [21]. Similarly, a recent study found that primary care physicians in England were equally unaware of the guidance, just 20%

reported being familiar with the national PA guidelines [22]. There was a greater awareness in this survey sample as half reported to have knowledge of this information; however, this still leaves a significant proportion uninformed. This is important as although knowledge alone is not enough to stimulate behaviour change, awareness is a determinant of it [23] and being aware that a certain behaviour is not optimal is an integral step in making a change [24].

Here, the majority (73%) had read about exercising after the cancer diagnosis in leaflets, but fewer (50%) had received verbal advice. Previous work has shown that PA is not routinely discussed by HCPs with cancer patients [25]. Yet, HCPs are the patients’ preferred source of information [26]. Patients have specifically expressed a wish for PA to be discussed during consultations and such discussion has been associated with higher levels of PA [27]. HCPs experience many barriers in the promotion of PA, including both lack of time and knowledge for discussions [28, 29]. Referral to CU Fitter™ only occurred for a minority (38%) and is perhaps indicative of continued issues with the promotion of PA in cancer care [28]. Similarly, low levels have been reported for exercise referral rates elsewhere [30]. Various solutions to these

challenges have been suggested including the following: educational modules for HCPs; development of better and accessible evidence-based PA resources; call for clear referral pathways; encouragement for HCPs to strengthen referral networks with PA specialists to enable detailed exercise prescription and/or access to cancer rehabilitation [28, 29].

A quarter to a third of the UK population meet the PA guidelines and this declines with age; 21% of men and 18% of women aged 65–74 years achieve the recommendations, dropping to 9 and 6%, respectively, in the over 75s [31]. There are no similar comprehensive data available yet for cancer survivors, but there is some evidence suggesting an increased rate of sedentary behaviour and reduction in PA levels post-diagnosis [8, 32, 33]. Adherence to recommended levels is lower in older survivors [34]. In the current study, 54/60 respondents provided pre- and post-diagnosis/current self-reported estimates of their PA levels. This showed that 39 and 46%, respectively, were classified as active for these time-points. This suggests that a significant proportion of the sample is in the desirable category for PA levels post-diagnosis, a finding similar to two previous large studies [35, 36]. Approximately half of a sample of 716 older people treated for cancer in England said they were moderately active more than once a week [35]. In another study of 975 cancer survivors, 45% were reported as physically active after their treatment [36]. In contrast, other studies found only 11 to 18% were active [7, 37]. Differences in sampling and measurement methods may account for some of this variance. The significant increase in self-assessed PA levels in the current study therefore requires confirmation with a randomised controlled study investigating long-term adherence and outcomes.

Research has found that health-related barriers to participating in exercise are particularly prevalent in a cancer population [33, 37]. A study in mixed cancer patients showed that the top 4 health barriers were illness or other health problems, joint stiffness, fatigue and pain [38]. This resonates with the current findings where half of respondents reported that they had to overcome feeling too unwell, tired or in pain to exercise. Evidence has also shown that health-related barriers often remain dominant, reflecting how cancer and its treatment-related side effects persist well after active treatment has ended [39]. Qualitative studies have highlighted additional concerns, such as facing loss of general physical conditioning making exercise more taxing, a loss of confidence in ability to exercise independently and fears about causing injury [13, 14, 40]. Similar apprehensions were apparent in our study where 45% reported loss of confidence as a barrier to being active and a third had worried about causing physical damage to themselves. Research has further revealed that survivors described social barriers such as embarrassment stemming from the impact of certain cancer treatments (e.g. bladder and bowel symptoms) [9, 13]. Our results showed that 18% experienced self-consciousness or embarrassment as a hindrance. Cancer

survivors clearly face unique barriers compared to the general population, which may make a programme such as CU Fitter™ particularly appealing and appropriate compared to mainstream services. Unique features include the following: a dedicated supportive environment; personalised activities aimed specifically at people with cancer from diagnosis onwards; delivered by instructors trained and familiar with this population; and services that are not time limited to a programme of a set number of sessions or weeks.

Respondents endorsed a wide range of benefits associated with participation in the exercise programme. The two most important gains were improving health and fitness and receiving social support. That health and fitness gains are primary beneficial outcomes for this population is well evidenced with a meta-analysis of exercise studies concluding that exercise should be implemented as part of cancer care [18]. The meta-analysis re-confirmed findings from a previous review [41] that the effects of supervised exercise were twice as large as those of unsupervised and recommended that future research needs to shift focus to understand how to optimise exercise participation, adherence and prescription. The current survey highlights how prominent social support is in terms of being a main facilitator to active behaviour. Macmillan [42] has reported closed exercise classes in particular, provide an important opportunity for social contact and mutual support, as well as the possibility of a safe environment with an instructor who understands the condition specific to participants. This was confirmed in another recent review that suggested that community-based interventions that meet in groups and are using behavioural change strategies were most effective in improving physical functioning and produced the largest effect sizes [43]. Other benefits reported by the current sample, such as having access to an exercise programme that is not limited to an end point and activities tailored to individual needs, provide direction for the exploration of factors that may optimise exercise interventions for people with cancer.

Research also suggests that exercise interventions for cancer survivors could be delivered through the use of technology [10, 44, 45]. A quarter of our respondents used exercise technology tools and half of the remaining non-users had an interest in exploring such technology in the future. A recent survey in 279 breast cancer patients confirmed a growing acceptance of technology-delivered interventions [44]. The majority (85%) was interested in remotely delivered exercise counselling, 80% said they would take part in a remotely delivered intervention and 68% would use an exercise app or website. Activity trackers, personalised feedback or feedback on how exercise is influencing mood or fatigue were described as the most helpful technology components. Preferences for technology-supported exercise interventions may vary among cancer survivors, but these findings are encouraging and could be another avenue for future research in this setting.

The current one-off survey design generated descriptive results and further research, ideally a prospective randomised controlled trial, is required to provide evidence of efficacy of this exercise programme. The small study sample had similar characteristics to people in the UK living with cancer. However, respondents had chosen to engage with the exercise programme and may already have had positive attitudes or an interest in exercise, biasing their views of PA in general and the programme specifically. Also, a convenience sample was used rather than a random approach method. The survey achieved a 65% response rate and we believe the majority of those attending the programme were canvassed, but non-responders' views and experiences are unknown and could be different.

Conclusions

This tailored cancer-specific exercise approach engaged cancer survivors and showed physical, psychological and social benefits from the programme. It is in-line with theory that individualised PA interventions that are easily accessible in the community can promote and support cancer survivors to be and stay active. These preliminary findings warrant further investigation.

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Compliance with ethical standards

Brighton and Sussex Medical School (BSMS) Research Governance and Ethics Committee (RefNo: 16/024/HAR) granted ethical approval for the study.

Conflict of interest Susan Catt and Helena Harder have no conflicts of interest to declare. Jan Sheward and Erica Sheward are Trustees of Cancer United™ (No.1155747), a registered cancer support charity based in West Sussex, UK through which the CU Fitter™ programme is delivered.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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