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ORIGINAL ARTICLE

Enhancing the experience of carers in the chemotherapy outpatient setting: an exploratory randomised controlled trial to test impact, acceptability and feasibility of a complex intervention co-designed by carers and staff

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Abstract

Purpose Supporting someone through chemotherapy can be emotionally and physically demanding. However, research has yet to establish the type of support carers require or the best way to provide this. This study tested the feasibility and acceptability of a complex intervention for carers that was co-designed by staff and carers of patients starting chemotherapy.

Methods Forty-seven carers were recruited, randomised between the intervention (n=24) and control (n=23) groups. A questionnaire was completed pre- and post-intervention measuring knowledge of chemotherapy and its side effects, experience of care, satisfaction with outpatient services, coping and emotional wellbeing. The intervention process was evaluated by carers and healthcare professionals (HCPs) in focus groups.

Results Recruitment to the study was unproblematic and attrition from it was low, suggesting the intervention and study processes were acceptable to patients and carers. Carers in receipt of the 'Take Care' intervention reported statistically significantly better understanding of symptoms and side effects and their information needs being more frequently met than carers in the control. Confidence in coping improved between baseline and follow-up for the intervention group and declined for the control although differences were insufficient to achieve statistical significance. There was no significant difference between the two groups' emotional wellbeing. HCP and carer focus groups confirmed the feasibility and acceptability of the intervention.

Conclusions The 'Take Care' intervention proved acceptable to carers and HCPs and demonstrates considerable promise and utility in practice. Study findings support the conduct of a fully powered RCT to determine the intervention's effectiveness and cost-effectiveness.

Keywords Carers · Chemotherapy · Support · Intervention

Background

Chemotherapy is the mainstay for treating some of the most common cancers including breast and colorectal cancer. Many regimens are administered in ambulatory settings. Consequently, patients benefit from remaining at home during treatment but have limited contact with hospital healthcare professionals (HCPs), usually only seeing them when treatment is

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administered [1]. Thus, patients and carers (their family/friends) assume responsibility for monitoring and managing treatment side effects and contacting HCPs if patients become unwell [2, 3].

It is now well established that carers perform many vital roles to ensure patients are supported and safe whilst at home [4–6]. These roles require assistance from HCPs. Indeed, clinical practice guidelines for psychosocial and supportive cancer care offered to adults with cancer produced by countries including the UK [7], USA [8], Canada [9] and Australia [10] as well as multinational organisations [11] stress the need for cancer care services to enhance support provided to carers.

Research exploring carers' experiences of supporting patients through chemotherapy depicts it as an intensely anxiety-provoking time characterised by concerns over managing patient side effects [2, 5]. Substantial numbers of carers are not provided with the information needed to help them care for patients at home; there appears considerable variation in practice with regard to the support they are provided [12]. A review of international literature relating to the information needs of family members of cancer patients showed that many experienced negative interactions with HCPs including being ignored, experiencing lack of empathy and compassion and receiving ambiguous and sometimes conflicting information [13]. Arguably, inadequate or conflicting information may result in carers being slow in recognising important changes in patients' health.

It is suggested that carers of cancer patients may themselves risk mental and physical ill health if their needs for information and support are not addressed and they perceive themselves ill equipped to care [14–16]. Their needs tend to be overlooked; carers' contribution is often unrecognised and underestimated by HCPs [17]. This may account for the dissatisfaction reported by carers supporting patients through chemotherapy [18]. They report 'feeling abandoned' [16], with their own needs for information and support often unmet [5, 12, 16].

Few intervention studies for improving the experiences and outcomes of carers of patients with cancer undergoing active treatment have been developed or tested [19–21]. None have been developed to support carers of people having chemotherapy. Most research addresses needs of carers of patients with advanced disease [22–27]. The most successful interventions are typically complex and frequently incorporate tailored nurse-led support to address carers' emotional, practical, social and information needs [20, 21, 28]. This research project tested the feasibility and acceptability of a complex intervention co-designed—together with staff—by carers of patients starting chemotherapy. It is the first randomised controlled trial (RCT)—albeit small and exploratory—to test an intervention specifically for carers in the context of chemotherapy treatment. It aimed to test proof of concept by studying feasibility, acceptability and potential to effect change in outcomes and experience of carers of people undergoing chemotherapy for cancer.

Methods

Design

The study adopted a two-phased mixed-method research design—underpinned by the MRC framework for developing and evaluating complex interventions [29]. It comprised i) a small exploratory RCT to provide evidence of impact and ii) embedded focus groups with carers and healthcare professionals to determine feasibility and acceptability of the intervention process and the instruments used (including timing of their administration) to measure impact.

'Take Care' intervention

The intervention was developed using experience-based co-design [30, 31]. This is an action research process that takes a user-centred orientation (by adopting a narrative story-telling approach) and centres around a participatory, collaborative co-design process [30]. The intervention—which became known as 'Take Care'—was co-designed by HCPs and carers from a cancer service in a large teaching hospital in England and the project steering group.

'Take Care' aimed to provide information and support to carers of people about to start a course of chemotherapy. It comprised a 19-min supportive/educative DVD, an accompanying booklet and 1-h protocol-guided group consultation conducted by one of two chemotherapy nurses trained in group facilitation The consultation was provided prior to patients' first cycle of treatment to groups of no more than five carers. During it, they watched the DVD and were provided opportunity to freely express concerns and ask questions. The DVD and booklet included information, advice and practical tips from carers and HCPs on topics including treatment side effects; impact of being a carer and dealing with emotions; and importance for carers of taking time out for themselves and accessing support. The booklet additionally provided hospital-specific information including maps and contact numbers. Carers were provided a copy of both the 'Take Care' DVD and booklet and were encouraged to consult both if and when they needed information and/or support during the patients' treatment.

Sample and setting

A sample of 40–50 carers was sought as recommended for an exploratory trial [32, 33]. A consecutive convenience sample of 47 was recruited. Carers were accessed through patients being treated with chemotherapy on a day unit in the large London teaching hospital where the intervention was developed. Members of the clinical team identified eligible patients. They were approached by the researcher at the pre-chemotherapy consultation and provided an information pack about the study. Pre-chemotherapy consultation sessions are information sessions usually delivered by nurses before chemotherapy treatment begins. Patients providing written consent, confirming their willingness for their carer to participate, introduced the researcher to their carer. Eligible patients were over 18 years, chemotherapy naïve, and due to start IV chemotherapy for breast, lung or colorectal cancer. These patient groups were recruited as they are amongst the most common cancers worldwide and are frequently treated with chemotherapy [34]. Eligible carers were over 18 years and nominated by patients as providing them with the majority of their support. Carers were excluded if they or the patients had comprehension difficulties through cognitive impairment or psychiatric illness or were unable to speak, read and write in English.

A subsample of carers took part in a focus group at the end of the study. Eligible carers had received the intervention and were willing to discuss their experiences of it. They were sampled purposively to provide variation in terms of carers' age, gender and relationship to the patient. Six carers were sought; 21 were approached, six consented and four attended (two others had been unable to contribute due to patients' declining health). A further focus group was attended by HCPs. Six HCPs were sampled purposively to include those that were either involved in intervention delivery or affected by its introduction.

Trial procedures

The study commenced after National Research Ethics Service Committee (ref: 11/LO/0100) and NHS Foundation Trust approvals (ref: RJ1 11/N140) were attained.

Participating carers completed baseline questionnaires (provided in person to the patient and/or carer when on the chemotherapy day unit) before they were randomly assigned between the intervention and control groups by simple randomisation using a table of randomly generated numbers. Randomisation and group allocation were undertaken by a member of the research team not involved in recruitment. Carers recruited to the intervention attended a Take Care group consultation within 2 weeks of randomisation. Questionnaire completion was repeated 4 weeks after baseline (questionnaires were sent and returned by post).

Instruments

Outcomes selected to measure the impact of the intervention were the following:

- Knowledge of chemotherapy and its side effects (investigator-developed series of nine 100-mm visual analogue scales (VASs))
- Unmet needs for information (seven items from the information subscale from the Supportive Care Needs Survey for Partners and Carers [SCNS-P&C44]) [35]
- Experience of care (investigator-designed 11-item Likert-scale tool)
- Perceived confidence in supporting friend/relative (investigator-developed six-item numerical rating scale based on Schwarzer and Fuchs [36])
- Emotional wellbeing (GHQ-12) [37]

Focus groups were facilitated by a member of the research team (VT) and guided by schedules addressing feasibility, acceptability and potential utility of the intervention; modifications required before testing in a larger trial; and the appropriateness of the questionnaire including its measures and timing; HCPs were additionally asked about their experiences of delivering the intervention and how this might fit with current practice.

Data analysis

Although the study was an exploratory trial, and inadequately powered to detect significant differences, scores were examined on the outcome measures pre- and post-intervention and between the intervention and control groups to assess trends in the data and likelihood of the intervention achieving the desired effect.

Analyses of covariance (ANCOVAs) were computed to determine differences in outcome by study arm. Follow-up scores of chemotherapy knowledge (individual 100 mm VAS scores), unmet need for information (sum of number of unmet needs for information subscale items of SCNS-P&C), perceived confidence (individual 0–10 NRS scores) and emotional wellbeing (total GHQ12 score: 0–3 scoring) were input as independent variables; baseline scores as covariates; and trial arm data as grouping factor.

Multinomial regression was used to analyse individual information need items scored on the information subscale of the SCNS-P&C. Logistic regression was used to analyse individual GHQ12 items and ordinal regression to analyse experience of, and satisfaction with, care items. Across all regression analyses, follow-up data were specified as the dependent variable and baseline scores and trial arm data as independent variables.

The feasibility of the trial design was explored through analysing recruitment, retention and attrition rates.

Focus groups were recorded digitally, transcribed and analysed thematically by a member of the research team (VT). Analysis drew on methods used in framework analysis [38]. A thematic framework was used to classify and organise data according to key themes and categories.

Results

Sociodemographic characteristics

The estimated recruitment rate of ten carers per month proved feasible in this particular study setting. Forty-seven carers were recruited to the study over 16 weeks in 2012 (Fig. 1); 24 were randomly assigned to the intervention and 23 to the control. Randomisation was acceptable to carers; none declined on learning that random allocation was required. Two carers allocated to the intervention arm did not attend the intervention session and two (one intervention, one control) were lost to follow-up (9 % attrition). All four were excluded from analysis. Participant characteristics were similar across study arms (Table 1).

Overall response rate to the baseline questionnaire was 59 % (47 out of 80 carers invited to participate took part).

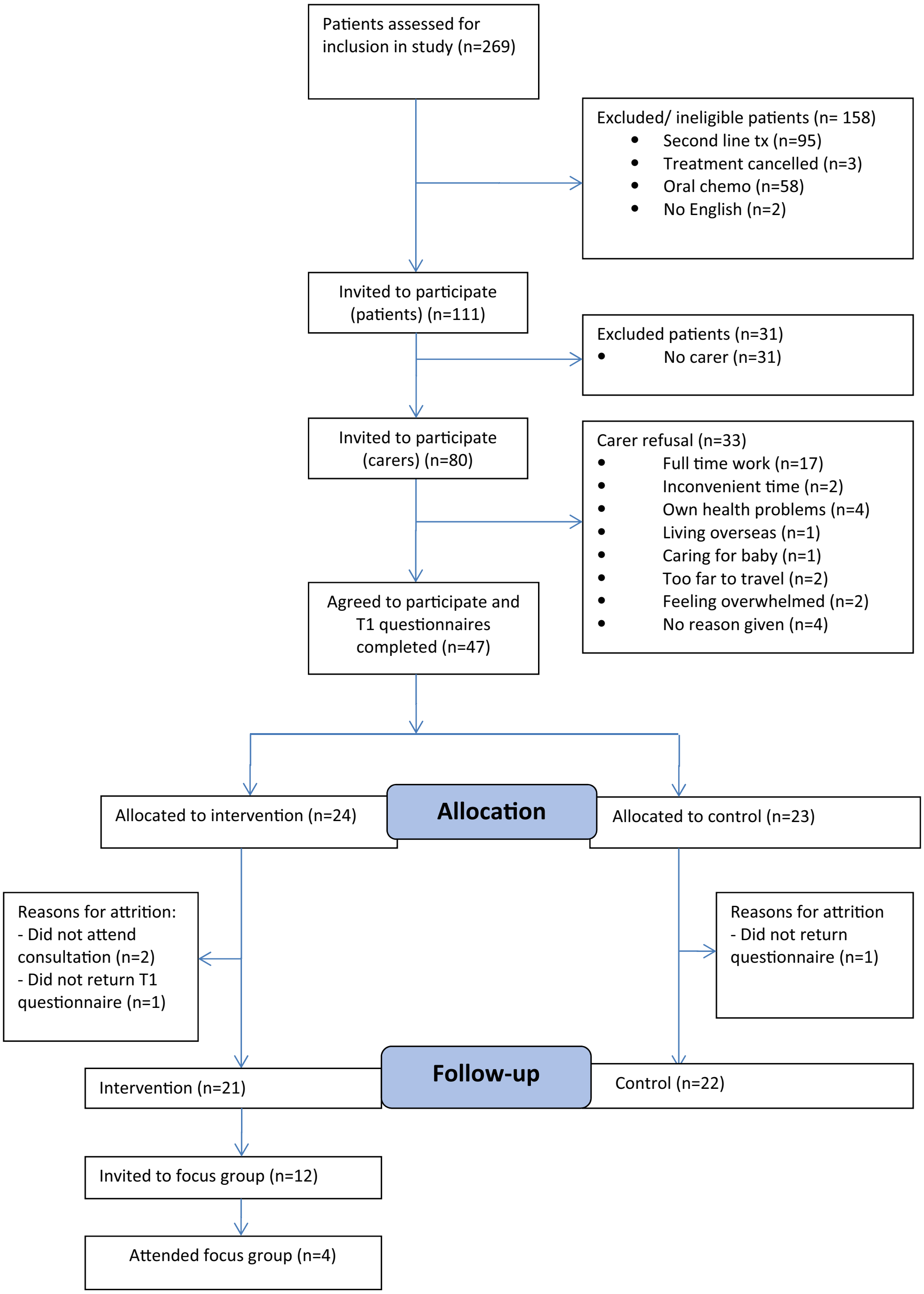

Fig. 1 Flow of participants through the study

Table 1 Carers' characteristics

	Intervention (*n*=21)	Control (*n*=22)	Total
Age mean (range)	54.10 (29–70)	51.50 (24–76)	52.77 (24–76)
	n (%)	*n* (%)	*n* (%)
Gender			
Male	7 (3)	8 (36)	15 (35)
Female	14 (67)	14 (64)	28 (65)
Patient diagnosis			
Breast cancer	7 (33)	7 (32)	14 (33)
Lung cancer	9 (43)	9 (41)	18 (42)
Colorectal cancer	5 (24)	6 (27)	11 (26)
Ethnicity			
White British	15 (71)	15 (68)	30 (70)
White Irish	1 (5)	0	1 (2)
Other White background	0	0	0
White and Black Caribbean	0	0	3 (7)
White and Black African	0	3 (14)	0
White and Asian	0	0	1 (2)
Other mixed background	1 (5)	1 (5)	2 (5)
Black or Black British: Caribbean	3 (14)	1 (5)	4 (9)
Black or Black British: African	1 (5)	1 (5)	1 (2)
Other Black background	0		0
Asian or Asian British: Indian	0	1 (5)	1 (2)
Asian or Asian British: Pakistani	0	0	0
Chinese	0	0	0
Other Asian background	0	0	0
Other ethnic group	0	0	0
Domestic status			
Single	5 (23)	2 (9)	7 (16)
Married	11 (52)	14 (64)	25 (58)
Widowed	1 (5)	0	1 (2)
Living with partner	4 (19)	4 (18)	8 (18)
Divorced/separated	0	2 (9)	2 (5)
Relationship to person with cancer			
Spouse/partner	11 (52)	8 (36)	19 (44)
Son or daughter	4 (19)	7 (32)	11 (26)
Parent	0	2 (9)	2 (5)
Friend	0	3 (14)	3 (7)
Other relative	6 (29)	2 (9)	8 (18)
Employment status			
Full time employed	5 (25)	7 (32)	12 (28)
Part time employed	4 (20)	5 (23)	9 (21)
Employed but on sick leave	0	0	0
Employed but on unpaid leave	0	0	0
Unemployed	2 (10)	1 (5)	3 (7)
Retired	8 (40)	6 (27)	14 (33)
Full-time or part-time education	0	0	0
Disabled	0	1 (5)	1 (2)
Full-time domestic responsibilities	1 (5)	2 (9)	3 (7)
Missing	1		1 (2)
Education			

Table 1 (continued)

	Intervention (n=21)	Control (n=22)	Total
No formal qualifications	1 (5)	2 (9)	3 (7)
GCSE/O levels or equivalent	10 (48)	7 (32)	17 (40)
A levels or equivalent	1 (5)	2 (9)	3 (7)
Diploma	2 (10)	2 (9)	4 (9)
Degree	2 (10)	6 (27)	8 (18)
A postgraduate qualification	5 (23)	3 (14)	8 (18)
Accommodation			
Owner-occupier	14 (67)	16 (73)	30 (70)
Renting from the council/housing association	4 (19)	4 (18)	8 (18)
Renting from a private landlord	3 (14)	2 (9)	5 (12)
Living in temporary accommodation	0	0	0
Other	0	0	0

Knowledge of chemotherapy side effects

Across all nine knowledge items, there was a consistent, and statistically significant, improvement in knowledge of chemotherapy side effects and their management in the intervention group when compared to the control (Table 2). Knowledge improved for all nine items in the intervention group whereas in the control group knowledge consistently declined.

Unmet need for information

There was a statistically significant increase in the proportion of people reporting that they did not have any information needs or that their information needs were being met between baseline and follow-up when comparing the intervention to the control. This applied to 8 out of the 12 items (Table 3). Four items that were not statistically different between groups related to discussing concerns with doctors; having information about the likely outcome of chemotherapy; having information about local healthcare services; and having help in finding out financial support and benefits for you and/or the person with cancer.

The average number of unmet information needs (SCNS-P&C Information Needs Scale) fell from 2.81 (SD 2.09) to 1.10 (1.48) for the intervention group and increased from 2.77 (SD 2.20) to 3.23 (SD 2.22) for the control (mean difference −2.15, 95 % CI −3.22 to −1.07, p<0.001), confirming what was found for the individual items (Table 3). The response "Yes, I have this need but it is not being met" was being used as a response less often in the intervention group compared to the control.

Experience of care

Experience of care between baseline and control did not differ significantly between groups except for one of the four items (See Table 4). The feeling that staff did not spend enough time with the carer (C4) improved between baseline and follow-up for the intervention group but worsened for the control group, and this difference between groups was statistically significant.

Satisfaction with care

Carers' satisfaction with care provided improved more for the intervention group than the control, and this difference was statistically significant for five of the seven items (Table 5). Satisfaction improved consistently across all satisfaction items in the intervention group whilst in the control group satisfaction more often than not declined.

Confidence in coping

Confidence in coping with the current situation tended to improve between baseline and follow-up for the intervention group and declined for the control group, but these differences were not sufficient to achieve statistical significance except for one item: How confident would you feel in supporting them [friend/relative] if their health gets worse (mean difference −1.643 [CI −2.96 to −0.32] p=0.016).

Emotional wellbeing

Change from baseline to follow-up did not differ significantly between the intervention and control groups for any of the 12 GHQ-12 items or the summed GHQ12 score.

Feasibility, acceptability and potential utility of the intervention

Focus group discussions with carers and HCPs echoed the statistical findings. Carers and HCPs reported the intervention

Table 2 Knowledge of chemotherapy

Knowledge of chemotherapy (0=insufficient, 100=excellent)	Intervention (n=21)				Control (n=22)				Mean diff.[a]	95 %	Prob<t
	Baseline		Follow-up		Baseline		Follow-up				
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)			
A1 How adequate was the information you have received from doctors/nurses about the benefits of chemotherapy?	60.9 (26.6)	66 (45)	76.0 (19.0)	81 (29)	57.5 (30.5)	71 (55)	50.4 (28.1)	55 (48)	23.4	(13.1–33.7)	<0.001
A2 How adequate was the information you have received from doctors/nurses about the side effects of your friend's /relative's chemotherapy?	69.9 (23.4)	78 (32)	80.6 (19.5)	87 (16)	70.8 (26.2)	80 (29)	55.8 (29.0)	64 (48)	25.3	(12.5–38.2)	<0.001
A3 How adequate was the practical advice you have received from doctors/nurses about managing chemotherapy symptoms?	54.6 (30.6)	65 (64)	73.4 (22.0)	79 (23)	55.7 (30.6)	61 (52)	48.1 (29.2)	52 (61)	26.1	(15.3–36.9)	<0.001
A4 How adequate was the information you have received from doctors/nurses about managing chemotherapy symptoms?	48.5 (28.7)	47 (61)	69.8 (24.1)	80 (24)	50.1 (30.1)	49 (63)	43.9 (27.0)	50 (47)	26.8	(14.4–39.1)	<0.001[b]
A5 How adequate is your knowledge regarding nausea?	50.6 (29.3)	51 (54)	69.9 (21.0)	70 (29)	60.9 (27.0)	63 (39)	50.1 (24.4)	53 (43)	23.8	(11.2–36.5)	<0.001
A6 How adequate is your knowledge regarding vomiting?	47.7 (30.5)	49 (55)	67.1 (23.0)	70 (31)	80.4 (90.1)	68 (40)	49.3 (24.9)	52 (50)	19.9	(4.7–35.1)	0.012
A7 How adequate is your knowledge regarding fatigue?	45.8 (29.2)	49 (58)	71.5 (19.9)	76 (31)	67.4 (24.3)	73 (40)	50.6 (21.9)	51 (34)	29.2	(16.9–41.5)	<0.001
A8 How adequate is your knowledge regarding low white blood cell count (neutropenia)?	39.3 (26.5)	31 (42)	56.4 (25.1)	58 (39)	51.0 (25.6)	48 (38)	36.4 (25.1)	38 (38)	24.6	(9.9–39.3)	0.002
A9 How adequate is your knowledge regarding low mood?	41.9 (28.0)	33 (39)	67.7 (23.1)	71 (36)	42.7 (24.7)	42 (28)	39.5 (23.3)	34 (34)	27.8	(14.6–41.1)	<0.001

[a] Mean difference at follow-up adjusting for baseline value

[b] Levene's test of group equality of variance, p=0.022

was educative; it enhanced knowledge of symptoms and side effects, prepared, empowered and reassured carers and increased confidence. The intervention appeared a source of support that helped legitimise and clarify the carer role and served to lessen anxiety about the chemotherapy process.

Overall, carers most valued receiving information through the DVD. They believed the visual aspect enabled them to digest and retain information easily. They spoke about the positive impact of watching it, particularly hearing other carers' experiences of chemotherapy.

Group delivery of intervention

There was variability in the numbers of carers that attended the group consultation sessions (range 1–5). The impression created by carers was that group dynamic and processes were compromised if too small. Groups of up to five carers—as intended—appeared optimal. Chemotherapy nurses that delivered the intervention agreed but spoke of challenges with managing differing personalities during group consultations—confirming the importance of training in group facilitation for chemotherapy nurses delivering the intervention.

Although healthcare professionals believed chemotherapy nurses were best placed to offer the support package, they highlighted the importance of liaising with clinical nurse specialists to identify vulnerable carers who would benefit most from it.

Timing of intervention

Healthcare professionals and the majority of carers thought the 'Take Care' package should be provided prior to chemotherapy, preferably on the same occasion that patients have their treatment explained to them, to enable carers time to prepare for it.

Representing diversity

The DVD and booklet both included images of patients and carers from BME communities. However, mention was made

Table 3 Information needs

Information needs	Time-point	Intervention n (%)			Control n (%)				
		Yes, not being met	Yes, is being met	No need	Yes, not being met	Yes, is being met	No need	χ^{2a}	*p*
B1 In the last month, did you need information on what the person with cancer's physical needs are likely to be?	Baseline	9 (43)	10 (48)	2 (10)	5 (23)	13 (59)	4 (18)	6.990	0.30
	Follow-up	3 (14)	11 (52)	7 (33)	8 (36)	9 (41)	5 (23)		
B2 In the last month, did you need information on what the person with cancer's emotional needs are likely to be?	Baseline[b]	10 (48)	9 (43)	2 (10)	10 (45)	9 (41)	2 (9)	9.824	0.007
	Follow-up	3 (14)	14 (67)	4 (19)	12 (55)	7 (32)	3 (14)		
B3 In the last month, did you need information on how to deal with symptoms and consequences of chemotherapy as they occur at home?	Baseline	7 (33)	13 (62)	1 (5)	10 (46)	9 (41)	3 (14)	15.184	0.001
	Follow-up	2 (10)	16 (76)	3 (14)	14 (64)	5 (23)	3 (14)		
B4 In the last month, did you need information about the benefits and side effects of treatments so you can participate in decision-making about the person with cancer?	Baseline	9 (43)	10 (48)	2 (10)	11 (50)	8 (36)	3 (14)	11.892	0.003
	Follow-up	2 (10)	15 (71)	4 (19)	12 (55)	8 (36)	2 (9)		
B5 In the last month, did you need to discuss your concerns with the doctors?	Baseline	4 (19)	11 (52)	6 (29)	6 (27)	9 (41)	7 (32)	2.072	0.355
	Follow-up	5 (24)	10 (48)	6 (29)	10 (46)	6 (27)	6 (27)		
B6 In the last month, did you need information relevant to your needs as a carer/partner?	Baseline	11 (52)	8 (38)	2 (10)	8 (36)	7 (32)	7 (32)	7.788	0.020
	Follow-up	3 (14)	14 (67)	4 (19)	11 (50)	6 (27)	5 (23)		
B7 In the last month, did you need information about the likely outcome of chemotherapy?	Baseline	6 (29)	15 (71)	0 (0)	8 (36)	11 (50)	3 (14)	4.483	0.106
	Follow-up	4 (19)	14 (67)	3 (14)	11 (50)	9 (41)	2 (9)		
B8 In the last month, did you need information about support services for carers/partners of people with cancer[a]?	Baseline	10 (48)	10 (48)	1 (5)	9 (41)	6 (27)	7 (32)	7.406	0.006
	Follow-up	4 (19)	14 (67)	3 (14)	13 (59)	4 (18)	5 (23)		
B9 In the last month, did you need information about complementary therapies[a]?	Baseline	8 (38)	7 (33)	6 (29)	7 (31)	6 (27)	9 (41)	5.649	0.017
	Follow-up[b]	2 (10)	15 (71)	4 (19)	8 (36)	5 (23)	8 (36)		
B10 In the last month, did you need help caring for the person with cancer on a practical level such as changing dressings, giving medications or bathing?	Baseline[c]	9 (43)	3 (14)	8 (38)	9 (41)	6 (27)	7 (32)	7.904	0.019
	Follow-up	3 (14)	4 (19)	14 (67)	7 (32)	8 (36)	7 (32)		
B11 In the last month, did you need information about local healthcare services?	Baseline	12 (57)	4 (19)	5 (24)	11 (50)	4 (18)	7 (32)	4.813	0.090
	Follow-up	4 (19)	10 (48)	7 (33)	10 (46)	6 (27)	6 (27)		
B12 In the last month, did you need help to find out financial support and benefits for you and/or the person with cancer[a]?	Baseline[c]	6 (28)	6 (28)	8 (36)	9 (41)	6 (27)	7 (32)	0.823	0.364
	Follow-up	5 (24)	7 (33)	9 (43)	9 (41)	6 (27)	7 (32)		

[a] χ^2 with 2° of freedom except B8, B9 and B12 that have 1° of freedom

[b] One missing value in the control group

[c] One missing value in the intervention group

that materials could have been more inclusive for people from diverse ethnic backgrounds.

Timing of outcome measures

All carers stated that 1 month was insufficient time to be able to measure comprehensively changes over time. They explained that the full effect of chemotherapy was experienced later in the process, by around the fourth or fifth cycle of treatment, depending on treatment regime administered.

Discussion

The exploratory study provided evidence of proof of concept for the 'Take Care' supportive intervention for carers.

Carers' satisfaction with care provided was significantly higher in the intervention group than in the control. The largest between-group difference related to the way carers' friend/relative's symptoms were managed. This may result from the intervention group's enhanced understanding of symptoms and side effects, possibly enhancing both their ability to report

Table 4 Experience of care

Experience of care		Time-point	*n* (%)						χ^{2a}	*p*
			Strongly agree	Agree	Neither agree/ disagree	Disagree	Strongly disagree	Missing		
C1 Experience of care: The staff have listened to what was worrying me	Intervention	Baseline	3 (14)	12 (57)	6 (29)	0	0	0	2.081	0.149
		Follow-up	5 (24)	12 (57)	3 (14)	1 (5)	0	0		
	Control	Baseline	4 (18)	10 (46)	7 (32)	1 (5)	0	0		
		Follow-up	4 (18)	9 (41)	5 (23)	4 (18)	0	0		
C2 Experience of care: I have felt my own views of my friend's/relative's illness were fully considered	Intervention	Baseline	3 (14)	9 (43)	6 (29)	3 (14)	0	0	3.222	0.073
		Follow-up	1 (5)	16 (76)	2 (10)	2 (10)	0	0		
	Control	Baseline	5 (23)	7 (32)	9 (41)	1 (5)	0	0		
		Follow-up	4 (18)	9 (41)	5 (23)	3 (14)	1 (5)	0		
C3 Experience of care: I have felt able to express myself and ask questions	Intervention	Baseline	7 (33)	9 (43)	3 (14)	2 (10)	0	0	2.468	0.116
		Follow-up	4 (19)	13 (62)	2 (10)	2 (10)	0	0		
	Control	Baseline	4 (18)	10 (45)	6 (27)	1 (5)	0	1 (5)		
		Follow-up	5 (23)	6 (27)	8 (36)	2 (9)	0	1 (5)		
C4 Experience of care: I have felt the staff did not spend enough time with me	Intervention	Baseline	1 (5)	2 (10)	5 (24)	10 (48)	3 (14)	0	6.063	0.014
		Follow-up	1 (5)	1 (5)	4 (19)	12 (57)	3 (14)	0		
	Control	Baseline	0	2 (9)	5 (23)	10 (46)	5 (23)	0		
		Follow-up	2 (9)	3 (14)	9 (41)	7 (32)	1 (5)	0		

[a] χ^2 with 1° of freedom for C1 and C2 and 2° of freedom for C3 and C4

symptoms early and boosting their confidence in seeking HCP support for their amelioration.

In terms of experience of care, changes observed between baseline and follow-up did not differ significantly between groups except for one of the four items—the feeling that 'staff did not spend enough time with the carer'. Given the nature and content of the intervention, it is not surprising that the intervention group reported having more sufficient time with HCPs. However, it was surprising that they showed little improvement across the other three items. Similarly, the level of emotional wellbeing appeared similar across the study groups. This was surprising, particularly given the positive findings from the carer focus group at the end of the study suggesting that carers felt reassured and supported emotionally by the intervention. Carers previously have reported feeling isolated by, and distressed with, their carer role and the emotional 'burden' it generates [5]. This outcome may, however, reflect the instrument used to measure emotional wellbeing. Although well validated, the GHQ-12 performs less well than other short tools including the Hospital Anxiety and Depression Scale [39] and was developed to detect psychiatric disorders rather than emotional distress.

Both carers and HCPs articulated strong support for the intervention in the focus groups and believed it increased carers' confidence and sense of empowerment. These beliefs were reflected in the outcome measures; confidence in caring for patients was higher in the intervention group on completing the study than in the control, but this failed to reach significance. This may have resulted from the exploratory study being underpowered (as would be expected given its scale and scope); the scale used to measure confidence in caring being insufficiently sensitive; or the timing of the follow-up questionnaires being unsuitable. Arguably, 1 month may have been an insufficient time period for carers to have developed confidence in their role. A follow-up questionnaire at 2 months may have been more suitable.

All participants valued the complementary components of the 'Take Care' package: DVD, booklet and consultation with the carer support nurse. The group consultation was appreciated by carers as it provided them opportunity to share experiences, exchange information, support others and be supported by HCPs. Further, it legitimised their carer role. Carer support nurses concurred that the group dynamic was important. This would suggest that future delivery of the intervention should incorporate group rather than individual carer

Table 5 Satisfaction with care

Satisfaction with care		Time-point	*n* (%)						χ^{2}[b]	*p*
			Not at all	Barely	Quite	Very	Completely	Missing		
C5 How satisfied were you with the information given to you about your relative's/friend's chemotherapy by doctors and nurses?	Intervention	Baseline	0	4 (19)	5 (24)	12 (57)	0	0	3.901[a]	0.048
		Follow-up	0	1 (5)	9 (43)	6 (29)	5 (24)	0		
	Control	Baseline	0	4 (18)	11 (50)	4 (18)	3 (14)	0		
		Follow-up	2 (9)	7 (32)	7 (32)	3 (14)	3 (14)	0		
C6 How satisfied were you with the extent to which you have been involved in decisions about care?	Intervention	Baseline	1 (5)	4 (19)	10 (48)	6 (29)	0	0	5.366	0.021
		Follow-up	0	3 (14)	7 (33)	7 (33)	4 (19)	0		
	Control	Baseline	0	6 (27)	10 (46)	4 (18)	2 (9)	0		
		Follow-up	2 (9)	6 (27)	9 (41)	4 (18)	1 (5)	0		
C7 How satisfied were you with the extent to which your worries and concerns have been considered?	Intervention	Baseline	2 (10)	3 (14)	7 (33)	9 (43)	0	0	5.808	0.016
		Follow-up	0	2 (10)	6 (29)	7 (33)	5 (24)	1 (5)		
	Control	Baseline	1 (5)	4 (18)	11 (50)	3 (14)	2 (9)	1 (5)		
		Follow-up	4 (18)	5 (23)	7 (32)	5 (23)	1 (5)	0		
C8 How satisfied were you with the nurses'/doctors' awareness of your needs?	Intervention	Baseline	3 (14)	4 (19)	5 (24)	8 (38)	1 (5)	0	3.383	0.066
		Follow-up	0	3 (14)	8 (38)	7 (33)	2 (10)	1 (5)		
	Control	Baseline	0	5 (23)	10 (45)	4 (18)	2 (9)	1 (5)		
		Follow-up	3 (14)	5 (23)	8 (36)	5 (23)	1 (5)	0		
C9 How satisfied were you with the extent to which your family's needs have been considered by doctors and nurses?	Intervention	Baseline	3 (14)	5 (24)	7 (33)	6 (29)	0	0	6.655	0.010
		Follow-up	1 (5)	2 (10)	9 (43)	5 (24)	4 (19)	0		
	Control	Baseline	1 (5)	7 (32)	9 (41)	4 (18)	0	1 (5)		
		Follow-up	4 (18)	4 (18)	10 (46)	1 (5)	3 (14)	0		
C10 How satisfied were you with the way in which your friend's/relative's symptoms were managed?	Intervention	Baseline	1 (5)	3 (14)	6 (29)	9 (43)	2 (10)	0	9.970	0.002
		Follow-up	0	1 (5)	3 (14)	12 (57)	5 (24)	0		
	Control	Baseline	1 (5)	2 (9)	12 (55)	4 (18)	2 (9)	1 (5)		
		Follow-up	2 (9)	5 (23)	7 (32)	7 (32)	1 (5)	0		
C11 How satisfied were you with the overall care that has been provided?	Intervention	Baseline	0	2 (10)	5 (24)	7 (33)	7 (33)	0	1.230	0.267
		Follow-up	0	2 (10)	4 (19)	11 (52)	4 (19)	0		
	Control	Baseline	2 (9)	3 (14)	11 (50)	4 (18)	2 (9)	0		
		Follow-up	1 (5)	5 (23)	7 (32)	8 (36)	1 (5)	0		

[a] Test of parallel lines significant

[b] χ^{2} with 1° of freedom

consultations with a support nurse. Apart from the economic benefits of group-delivered interventions, they are effective in reducing psychological and emotional consequences of cancer and often yield better coping outcomes than those using other methods of delivery [28].

Results of the exploratory trial indicate the intervention would be amenable to a large-scale trial. Some revision to outcome measures is indicated. Whilst trends were detected in enhanced perceived confidence in caregiving following the intervention, a scale to measure preparedness for caregiving such as that developed by Henriksson et al. [40] would appear more suitable to capture changes generated by the intervention. Future studies should incorporate such a measure.

Future research efforts should be directed at maximising response rates and minimising attrition by offering the intervention at times to best accommodate carers who work full time or have other responsibilities. Both carers and HCPs advocated delivering the intervention as early as possible in the chemotherapy process. There was consensus the chemotherapy consultation may be the most appropriate time to offer the intervention. HCPs suggested allowing additional time at the end of the consultation to address carers' needs. However, participants stressed that it should also be available at other times to ensure carers who do not attend the patient's consultation could still access it.

Strengths and weaknesses of the study

It is important to recognise the limitations of this study in addition to those already raised. The small sample size may limit generalisability. The exploratory trial was conducted in one centre, and there may be aspects of feasibility we have not tested. For example, it may not be possible to accommodate a group consultation for carers into clinical pathways in the same manner at other centres.

The responses of participants to the questionnaires were based on self-report and possibly subject to recall bias. Also, only three tumour types were included in the trial sample: breast, lung and colorectal. This means that findings cannot be generalised to carers in other tumour groups. Another limitation is that the study recruited primarily Caucasian carers and only English speakers. Consequently, the views of carers from Black and minority ethnic groups are underrepresented.

Conclusion

This study tested, through an exploratory trial, an intervention designed to support carers of people about to receive chemotherapy. The intervention proved acceptable to both carers and HCPs and demonstrated considerable promise and utility in practice. The findings of this study suggest the intervention warrants investigation within the context of a fully powered RCT to determine effectiveness and cost-effectiveness.

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