Results

Participant's characteristics at baseline

Figure 1 shows the flow of participants in the course of the study. Of the 88 patients assessed for eligibility, 26 were excluded. The reasons for exclusion were: not meeting inclusion criteria (n= 13), declined to participate in the study (n= 6), and participants home too far from study site (n= 7).
Sixty two participants were enrolled and signed informed consent and randomly allocated to CBT-AP and UC group.

Using intention-to-treat analysis, 30 patients from intervention and 28 patients from usual-care groups entered to analysis.

Figure 1 Study flow chart among breast cancer patients undergoing chemotherapy in TASH, Ethiopia, 2022

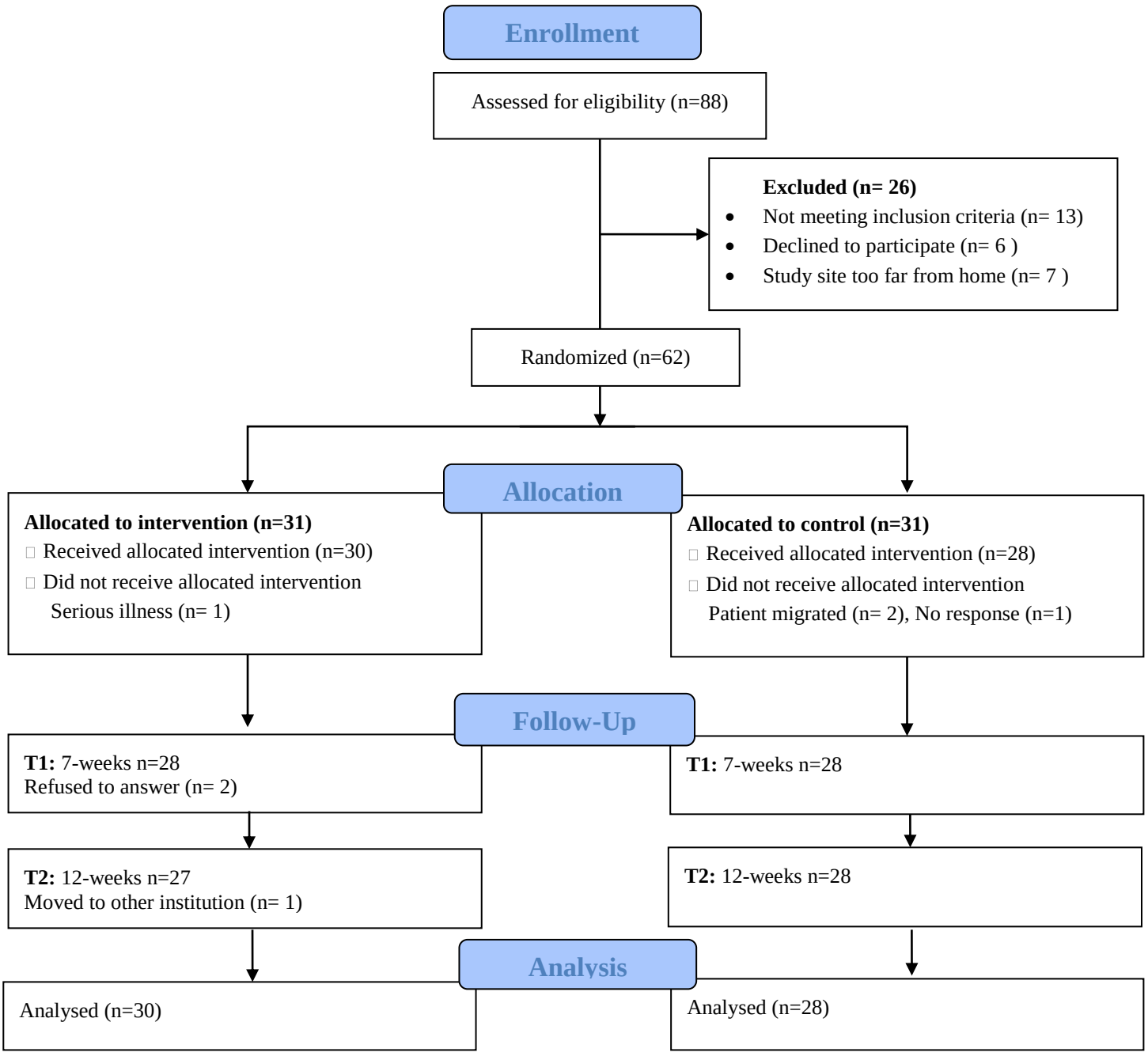

Table 1 Baseline socio-demographic and clinical characteristics of breast cancer patients undergoing chemotherapy in TASH, Ethiopia, 2022

Characteristics	CBT-AP		Usual care (UC)		Significance
Age in years					
Mean (SD)	40.2(10.9)		42.5(12.3)		t=0.76, P=0.45
Educational status	n	%	n	%	
No formal education	1	3.3	3	10.7	X^2=0.04,
Primary education	9	30.0	6	21.4	P=0.75
Secondary education	11	36.7	11	39.3	
Above secondary education	9	30.0	8	28.6	
Occupational status					
Housewife	17	56.7	12	42.9	X^2=0.14,
Government employed	4	13.3	5	17.9	P=0.30
Merchant	2	6.7	1	3.6	
Daily labourer	6	20.0	3	10.7	
Private employed	1	3.3	7	25	
Religion					
Orthodox Christianity	20	66.7	18	64.3	X^2=0.04,
Muslim	5	16.7	2	7.1	P=0.80
Protestant	2	6.7	6	21.4	
Catholic	3	10.0	2	7.1	
Marital status					
Single	9	30.0	5	17.9	X^2=0.90,
Married	12	40.0	14	50	P=0.50
Divorced	8	26.7	8	28.6	
Widowed	1	3.3	1	3.6	
Stage of cancer					
Stage I	3	10	2	7.1	X^2=0.18,
Stage II	15	50	10	35.7	P=0.17
Stage III	11	36.7	13	46.4	
Stage IV	1	3.3	3	10.7	
ECOG-PS					
ECOG I	2	6.7	1	3.6	X^2=0.18,
ECOG II	28	93.3	25	89.3	P=0.19
ECOG III	-	-	2	7.1	
Chemotherapy cycle					
<4	18	60	8	28.6	Z=2.82,
4-5	3	10	4	14.3	P =0.005
6-7	8	26.7	7	25.0	
>7	1	3.3	9	32.1	
Comorbidity					
Yes	5	16.7	11	39.3	X^2=0.25,
No	25	83.3	17	60.7	P=0.06
Histological classification					

Ductal carcinoma	27	90	26	92.9	
Lobular carcinoma	1	3.3	1	3.6	X^2=0.02,
Medullary carcinoma	1	3.3	-	-	P=0.30
Mucinous carcinoma	1	3.3	-	-	
Papillary carcinoma	-	-	1	3.6	
Time since diagnosis (month)					
Mean	10.20		12.07		t=0.67,
SD	12.46		7.97		P=0.50
Tumour stage					
TX	3	10	2	7.1	
T1	6	20	5	17.9	X^2=0.07,
T2	10	33.3	11	39.3	P=0.61
T3	1	33.3	7	25	
T4	3	3.3	3	10.7	

Table 2 Baseline assessment of outcome variables among breast cancer patients undergoing chemotherapy in TASH, Ethiopia, 2022.

Outcome variables	CBT-AP		Usual care (UC)		Statistics, P-value
	Mean	SD	Mean	SD	
Fatigue					
BFI-9	3.84	1.67	4.31	2.35	t=0.88, P=0.38
Depression					
PHQ-9	0.96	0.63	1.14	0.55	t=1.16, P=0.25
Quality of Life					
EORTC QLQ-C30					
Physical functioning	65.78	20.5	66.20	19.28	t=0.79, P=0.94
Role functioning	66.67	27.7	64.28	28.22	t=0.32, P=0.75
Emotional functioning	57.78	25.6	61.30	25.0	t=0.53, P=0.60
Cognitive functioning	68.33	31.4	73.21	24.15	t=0.66, P=0.51
Social functioning	63.88	32.4	51.20	31.73	t=1.50, P=0.14
Fatigue	56.30	23.8	51.20	22.08	t=0.84, P=0.40
Nausea and vomiting	37.22	36.27	29.17	33.21	t=0.88, P=0.38
Pain	46.11	29.25	39.28	23.66	t=0.97, P=0.34
Dyspnea	21.11	27.0	19.05	23.00	t=0.31, P=0.75
Insomnia	46.66	35.66	19.04	23.00	t=3.47, P < 0.001
Appetite loss	53.33	32.28	48.81	30.74	t=0.55, P=0.58
Constipation	30.00	36.50	44.04	39.60	t=1.41, P=0.17
Diarrhoa	6.67	18.4	8.33	19.51	t=0.34, P=0.74
Financial difficulties	73.33	33.2	84.52	21.24	t=1.52, P=0.14
EORTC QLQ-BR45					
Functional scales					
Body image	67.78	29.18	58.93	26.83	t=1.20, P=0.24
Sexual functioning	87.22	19.41	89.28	18.26	t=0.42,P=0.68
Sexual enjoyment	50.86	13.87	48.98	13.02	t=0.53, P=0.60
Future perspective	42.22	40.05	33.33	36.28	t=0.88, P=0.38
Breast satisfaction	40.80	36.88	71.79	22.00	t=3.73, P=0.43
Symptom scales/items					
Systemic therapy side effects	48.25	20.65	49.32	15.56	t=0.22, P=0.83
Breast symptoms	21.94	16	30.95	21.25	t=1.83, P=0.07
Arm symptoms	32.96	26.66	38.49	25.38	t=0.81, P=0.42
Upset by hair loss	57.10	35.94	60.32	31.16	t=0.34, P=0.73
Target symptom scales					
Endocrine therapy	31.0	22.28	31.07	17.16	t=0.01,P=0.99
Endocrine sexual	18.75	26.85	14.81	28.20	t=0.33, P=0.75
Skin mucosis	28.14	21.24	24.40	18.23	t=0.72, P=0.47
Global Health and Quality of life	93.88	43.87	47.32	19.51	t=5.16, P=0.44

Adverse events: No

Outcome measures

Table 3 Effect of CBT-AP on cancer related fatigue and depression among breast cancer patients (CBT-AP group: n = 30, UC group: n = 28)

Variables/ Condition	Baseline		End of intervention		3 months follow up			P-value	ηp^2	F
	Mean	SD	Mean	SD	Mean	SD				
Fatigue										
Intervention	3.84	1.70	2.52	1.85	2.91	1.89	Within subject(Time)	0.911	0.002	0.093
Control	4.31	2.35	5.27	1.98	5.40	2.13	Group×time	0.001	0.114	6.92
							Between subject	0.000	0.206	13.96
Depression										
Intervention	1.00	0.63	0.53	0.38	0.56	0.44	Within subject (Time)	0.835	0.003	0.180
Control	1.14	0.54	1.53	0.70	1.73	0.78	Group × time	0.000	0.141	8.85
							Between subject	0.000	0.436	41.75

Table 4 Effect of CBT-AP on QoL (EORTC QLQ C-30 functioning and symptom scales) among breast cancer patients undergoing chemotherapy (CBT-AP group: n=30, control group: n=28)

Variables/ Condition	Baseline (T1)		End of treatment (T2)		3 months of follow-up(T3)		Type of effect	P-value	ηp^2	F
	Mean	SD	Mean	SD	Mean	SD				
GHS/QoL										
Intervention	94.0	43.8	145.1	45.2	133.2	45.8	Within subject (Time)	0.21	0.029	1.60
Control	47.3	19.5	33	15.9	39.6	17.6	Group*time	0.00	0.232	16.27
							Between group	0.00	0.659	104.44
Physical functioning										
Intervention	65.7	20.5	75.34	20.62	73.83	20.31	Within subject(Time)		0.003	0.139
Control	66.19	19.28	54.28	19.26	53.81	20.68	Group*time	0.007	0.089	5.277
							Between group	0.001	0.183	12.09
Role functioning										
Intervention	66.67	27.68	72.81	29.51	73.00	29.33	Within subject(Time)	0.787	0.004	0.240
Control	64.28	28.22	64.29	28.22	50.00	22.68	Group*time	0.011	0.081	4.736
							Between group	0.010	0.118	7.218
Emotional functioning										
Intervention	57.78	25.61	74.41	23.55	72.56	24.59	Within subject(Time)	0.941	0.001	0.060
Control	61.31	24.97	50.60	27.95	43.15	31.26	Group*time	0.003	0.101	6.069
							Between group	0.000	0.230	16.15
Cognitive functioning										
Intervention	68.33	31.36	75.40	23.12	73.26	25.03	Within subject(Time)	0.299	0.022	1.221
Control	73.21	24.15	53.57	28.46	55.36	29.42	Group*time	0.009	0.083	4.90
							Between group	0.000	0.224	15.60
Social functioning										
Intervention	63.88	32.48	78.30	24.75	72.75	24.84	Within subject(Time)	0.346	0.019	1.07
Control	51.19	31.73	39.28	26.92	60.04	31.47	Group*time	0.007	0.088	5.22
							Between group	0.000	0.281	21.09
Fatigue										
Intervention	56.29	23.87	38.78	24.45	41.53	23.85	Within subject(Time)	0.911	0.002	0.09
Control	51.19	22.08	61.51	19.24	69.05	23.87	Group*time	0.001	0.114	6.92
Nausea and vomiting										
Intervention	37.22	36.27	17.54	22.55	17.76	23.81	Within subject(Time)	0.562	0.009	0.513
Control	29.16	33.22	25.00	28.86	42.26	30.25	Group*time	0.028	0.070	4.06
							Between group	0.006	0.131	8.13
Pain										
Intervention	46.11	29.25	29.28	27.42	35.33	28. 11	Within subject(Time)	0.951	0.001	0.050
Control	39.28	23.66	56.55	18.34	48.81	24.82	Group*time	0.003	0.108	6.54
							Between group	0.002	0.168	10.94

Dyspnoea										
Intervention	21.11	26.95	12.52	18.13	18.27	20.51	Within subject(Time)	0.939	0.001	0.063
Control	19.05	23.00	28.57	26.78	34.52	26.42	Group*time	0.723	0.006	0.325
							Between group	0.000	0.263	19.27
Insomnia										
Intervention	46.66	35.66	37.79	29.984	37.95	29.62	Within subject(Time)	0.523	0.012	0.653
Control	19.05	23.00	28.57	26.781	55.95	31.50	Group*time	0.000	0.137	8.739
							Between group	0.106	0.047	2.69
Appetite loss										
Intervention	53.33	32.28	31.85	30.43	28.44	29.35	Within subject(Time)	0.753	0.005	0.284
Control	48.81	30.74	55.95	27.29	58.33	32.23	Group*time	0.022	0.068	3.96
							Between	0.001	0.395	35.26
Constipation										
Intervention	30.00	36.46	18.82	31.14	19.64	26.97	Within subject(Time)	0.168	0.032	1.814
Control	44.05	39.60	45.24	37.64	48.81	35.69	Group*time	0.085	0.045	2.53
							Between group	0.001	0.192	12.85
Diarrhoea										
Intervention	6.66	18.36	6.33	12.63	7.93	16.06	Within subject(Time)	0.429	0.016	0.852
Control	8.33	19.51	16.66	26.45	17.85	27.94	Group*time	0.399	0.017	0.926
							Between group	0.014	0.107	6.454
Financial difficulties										
Intervention	73.33	33.22	52.16	36.79	63.47	33.18	Within subject(Time)	0.429	0.016	0.853
Control	84.52	21.24	85.71	16.79	73.81	30.57	Group*time	0.004	0.099	5.912
							Between group	0.003	0.152	9.710

Brief summary

Analysis was done based on 30 patients in the CBT-AP and 28 patients in the UC group. CBT-AP group was found to have lower fatigue score (F (2,108) =13.96, $p < 0.001$, $\eta p2 = .206$), lower depression score (F (1, 54) =.41.75, $p < .001$, $\eta p2 = .436$), and higher global health status/ quality of life score (F (1, 54) = 104.44, $p < .001$, $\eta p2 = .659$) compared to UC group. The group * time interaction has also revealed significant reduction of fatigue and depression in the CBT-AP group than UC group (F (2,108) =6.92, p=0.001, $\eta p2 = .114$), (F (2, 108) = 8.85, $p < .001$, $\eta p2 = .141$) respectively. CBT-AP appears to be effective in reducing fatigue, depression and in improving QoL of breast cancer patients undergoing chemotherapy. It is highly recommended to integrate CBT-AP intervention in routine cancer care.

Registration PACTR, PACTR202008881026130, Registered 24 August 2020, http://www.pactr.org/ PACTR202008881026130