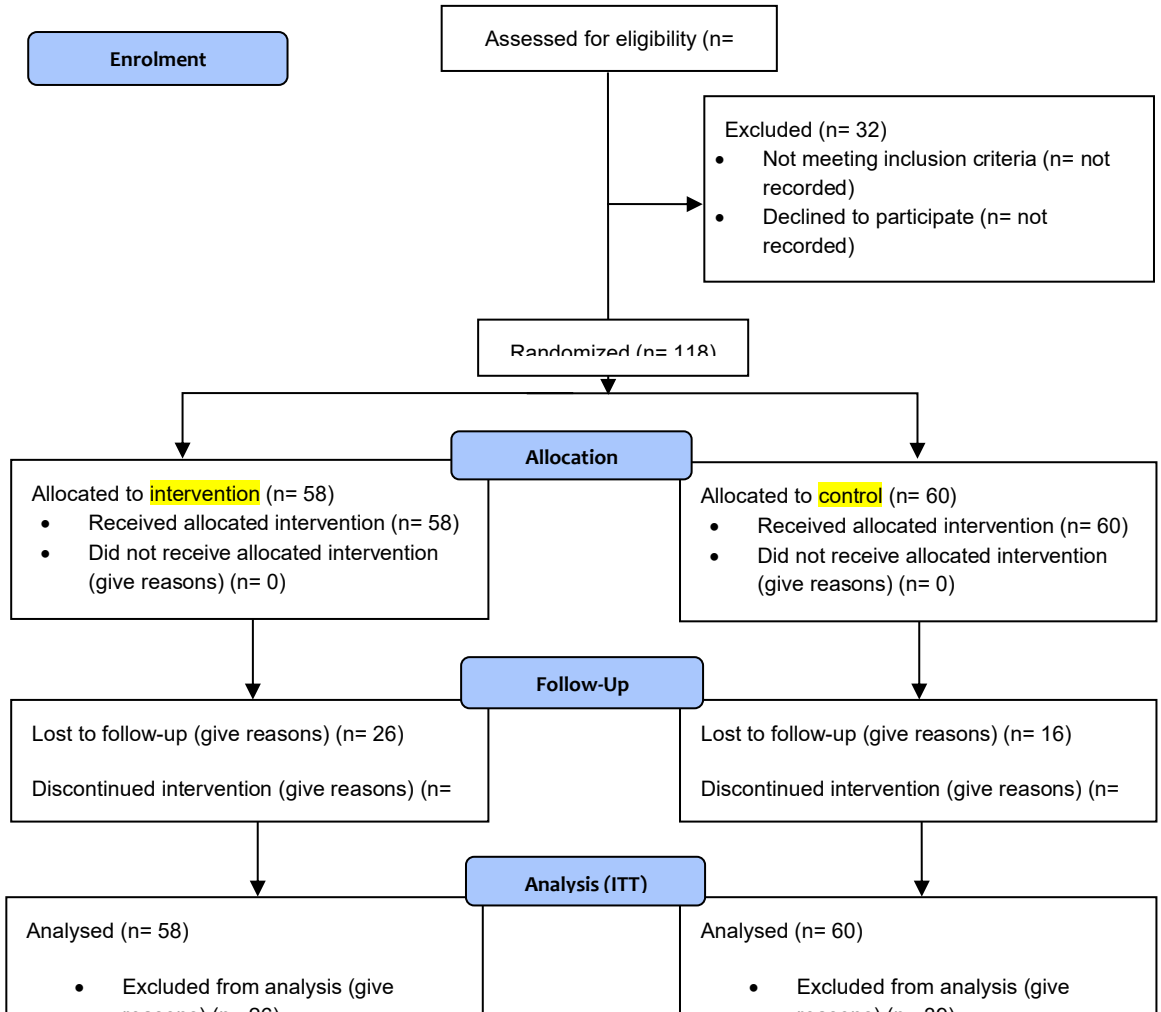
ReFresh Pilot RCT – Basic Results Summary for ISRCTN

1. Participant Flow

A total of 150 individuals expressed interest in the ReFresh pilot study. Of these, 118 participants completed baseline assessments and were randomised into either the intervention group (n = 58) or the waitlist control group (n = 60). Over the 12-week study period, 42 participants withdrew, resulting in an overall attrition rate of 35.6%. Attrition was higher in the intervention group (44.8%) than the control group (26.7%). Participants who completed endpoint assessments were included in both ITT and PP analyses.

Stage	Intervention (n = 58)	Control (n = 60)	Total (N = 118)
Assessed for eligibility	–	–	150
Randomised	58	60	118
Received allocated intervention	58	60	118
Lost to follow-up (attrition)	26 (44.8%)	16 (26.7%)	42 (35.6%)
Completed endpoint assessment	32	44	76
Analysed (ITT)	58	60	118



2. Baseline Characteristics

Characteristic	Intervention (n = 58)	Control (n = 60)	Total (N = 118)
Age (mean ± SD)	66.3 ± 7.5	67.1 ± 8.2	66.7 ± 7.9
Sex (% female)	48.3%	45.0%	46.6%
Years since diagnosis (mean ± SD)	6.4 ± 3.1	6.7 ± 3.5	6.6 ± 3.3
PFS baseline score (mean ± SD)	3.8 ± 1.2	3.9 ± 1.1	3.85 ± 1.15
MS-FSE baseline score (mean ± SD)	34.5 ± 8.3	35.2 ± 9.1	34.85 ± 8.7

3. Outcome Measures

Measure	Group	Baseline Mean (SD)	Endpoint Mean (SD)	Change Mean (SD)	T test (Intervention vs. Control mean change)
Fatigue Measures					
PFS	Intervention	56.18 (14.93)	53.13 (16.24)	-3.05 (9.54)	P=0.102
	Control	57.31 (13.09)	57.52 (13.04)	0.21 (7.84)	
MFIS	Intervention	40.61 (15.60)	39.85 (18.62)	-0.75 (11.38)	P=0.33
	Control	42.70 (14.01)	42.87 (15.43)	0.16 (8.25)	
Secondary Measures					
MS-FSE	Intervention	47.06 (25.12)	52.52 (24.13)	5.45 (13.80)	P=0.05*
	Control	45.77 (20.60)	44.50 (20.28)	-1.27 (14.18)	
PSQI	Intervention	9.47	9.17 (2.99)	-0.30 (1.21)	P=0.09

		(3.03)			
	Control	10.49 (3.24)	10.16 (3.02)	-0.39 (1.46)	
PDQ	Intervention	26.10 (15.92)	29.34 (20.84)	3.25 (15.35)	P=0.47
	Control	29.49 (16.09)	32.00 (24.56)	2.84 (17.27)	
PAS	Intervention	24.79 (11.72)	25.26 (11.31)	0.48 (5.06)	P=0.72
	Control	25.59 (10.71)	25.95 (9.73)	0.36 (5.78)	
GDS	Intervention	4.41 (3.80)	5.00 (4.54)	0.59 (1.86)	P=0.25
	Control	4.91 (3.66)	5.91 (4.18)	1.00 (1.94)	

4. Adverse Events

There were no anticipated or unanticipated adverse events associated with the ReFresh study. Participants reported no serious or life-threatening complications related to their involvement.