# The feasibility and acceptability of an early intervention in primary care to prevent Chronic Fatigue Syndrome (CFS) in Adults: Randomised controlled <u>trial.</u>

#### Figure 1: CONSORT Early Intervention in Fatigue S



Baseline economic characteristics of the randomised population	Treatment group	
	Control (n=16)	Intervention (n=28)
EQ5D-5L		
Median EQ5D-5L (25 <sup>th</sup> , 75 <sup>th</sup> centiles)	0.710 (0.581, 0.790)	0.716 (0.492, 0.811)
WPAI: GH 1		
Number in paid work (%)	13 (81)	18 (64)
Median hours missed from work due to	0.0 (0., 4)	0.0 (0, 2)
health problems in the past seven days (25 <sup>th</sup> , 75 <sup>th</sup> centiles)*		
Median hours missed from work due to	0.0 (0,7.6	1.0 (0, 15)
other reasons in the past seven days (25 <sup>th</sup> , 75 <sup>th</sup> centiles)*		
Median hours worked in the past seven days (25 <sup>th</sup> , 75 <sup>th</sup> centiles)*	30.0 (10, 40)	24.5 (16, 38)
Median health problems affected productivity while working in the past seven days (25 <sup>th</sup> , 75 <sup>th</sup> centiles)**	4.0 (3, 7)	4.0 (2, 6)
Median health problems affected productivity other than working in the past seven days (25 <sup>th</sup> , 75 <sup>th</sup> centiles)	6.0 (5, 8.0)	5.5 (3.5., 8)
*Only answered by those patients who are of group). **Only answered by those patients of the past seven days (11 in control group, 17	who are currently in paid work an	

#### **Table 2: Primary Outcomes**

Recruitment	n
Assessed	90
Included	44
Excluded	46

Reasons for exclusion	n
Fatigue>4months	11
Fatigue resolved	7
Total fatigue exclusions	18
Missing blood results	3
Blood screening exclusions	17
Blood screening exclusions	17

### Table 3: 6 Months Clinical and Health Economic Outcomes

6 month clinical and health economic outcomes	Control group mean (95% confidence interval ), n	Intervention group mean (95% confidence interval ), n
Chalder Fatigue score	14.7 (10.6,18.9), 16	12.3 (9.3, 15.3), 20
Pain VAS	18.9 (5.8, 31.9), 16	22.1 (8.5, 35.7), 19
SF-36 Physical Function score	84.4 (72.4, 96.3), 16	76.8 (65.1, 88.4), 20
HADS Anxiety score	7.8 (4.9, 10.6), 16	7.8 (5.4, 10.3), 19
HADS Depression score	4.6 (2.9, 6.2), 16	4.9 (3.0, 6.9), 19
EQ-5D-5L score	0.774 (0.677, 0.870), 16	0.749 (0.643, 0.855), 19
Hours missed from work due to health problems in the past seven days	1.8 (-0.4, 4.1), 11	5.3 (-2.5, 13.1), 15
Health problems affected productivity while working in the past seven days	3.0 (1.6, 4.4), 12	1.8 (0.6, 3.0), 13
	Control group AUC (SD) (n=16)	Intervention group AUC (SD) (n=20)
QALY	0.371 (0.326, 0.416)	0.346 (0.293, 0.400)

## Table 4: Serious Adverse Events

Type of event	n	Nature of the event
Expected adverse events	0	
Unexpected adverse events	1	A&E admission with cardiac symptoms

### Table 5: Adherence

Allocated to usual care	n=16	Allocated to usual care plus early intervention	n=28
Received allocated care	n=16	Received allocated intervention	n=19
Did not receive allocated care	n=0	Did not receive allocated intervention	n=9

# Table 6: Loss of Follow Up

Lost to follow up	<u>n</u>	Reasons
Usual care	0	
Discontinued intervention	0	
No Response	6	
Did not attend any intervention	2	
Discontinued Intervention	6	2 gave reasons both were not accepting of the therapeutic model