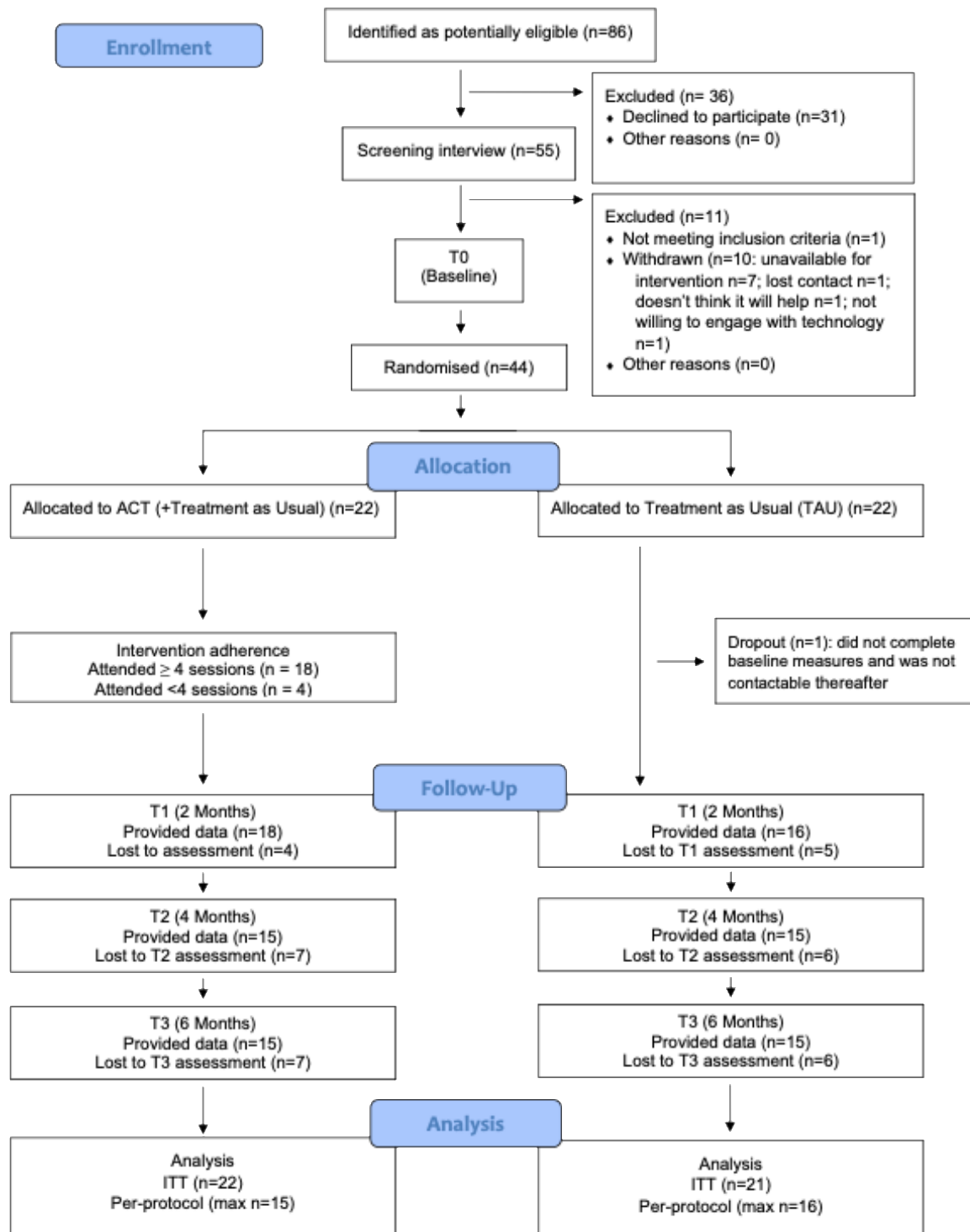## Summary of results

Figure 1. Consolidated Standards of Reporting Trials (CONSORT) Diagram for Participant Note: ITT = Intention-to-Treat. Per-protocol (max n) = maximum number of participants at any of the follow-ups (for the ACT (plus TAU) condition this included only those who had attended ≥4 intervention sessions).

Table 1. Sociodemographic information, clinical data and screening scores for anxiety and depression in ACT (+TAU; n = 22) and TAU (n = 22).

	ACT +TAU	TAU	Total
	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	48.75 (13.84)	51.45 (12.00)	50.10 (12.87)
	n (%)	n (%)	n (%)
Gender			
Female	14 (63.6)	13 (59.1)	27 (61.4)
Male	8 (36.4)	9 (40.9)	17 (38.6)
Ethnicity			
Asian/Asian British	5 (22.7)	1 (4.5)	6 (13.6)
Arab/Arab British	0 (0.0)	1 (4.5)	1 (2.3)
Black/Black British	1 (4.5)	0 (0.0)	1 (2.3)
Dual Heritage	0 (0.0)	2 (9.1)	2 (4.5)
White	16 (72.7)	18 (81.8)	34 (77.3)
White British	12 (54.5)	13 (59.1)	25 (56.8)
White Irish	1 (4.5)	1 (4.5)	2 (4.5)
White Other	3 (13.6)	4 (18.2)	7 (15.9)
Employed	13 (59.1)	13 (59.1)	26 (59.1)
Full-time employment	9 (40.9)	8 (36.4)	17 (38.6)
Part-time employment	4 (18.2)	5 (22.7)	9 (20.5)
Comorbid conditions	15 (68.2)	17 (77.3)	32 (72.7)
Anxiety disorder	3 (13.6)	4 (18.2)	7 (15.9)
Arthritis	1 (4.5)	5 (22.7)	6 (13.6)
Cardiovascular disease	2 (9.1)	3 (13.6)	5 (11.4)
Chronic pain	1 (4.5)	5 (22.7)	6 (13.6)
Depressive disorder	0 (0.0)	2 (9.1)	2 (4.5)
Diabetes	3 (13.6)	1 (4.5)	4 (9.1)
Epilepsy	0 (0.0)	2 (9.1)	2 (4.5)
FND	0 (0.0)	2 (9.1)	2 (4.5)
Migraine	3 (13.6)	3 (13.6)	6 (13.6)
PTSD	2 (9.1)	1 (4.5)	3 (6.8)
Spinal disorder symptoms	1 (4.5)	3 (13.6)	4 (9.1)
Other	13 (59.1)	12 (54.5)	25 (56.8)
Current medications			
Anticonvulsive	2 (9.1)	5 (22.7)	7 (15.9)
Antidepressive	2 (9.1)	9 (40.9)	11 (25.0)
Antidiabetic	3 (13.6)	2 (9.1)	5 (11.4)
Antihistamine	2 (9.1)	2 (9.1)	4 (9.1)
Antipsychotic	1 (4.5)	0 (0.0)	1 (2.3)
Asthma	1 (4.5)	3 (13.6)	4 (9.1)
Cardiovascular	6 (27.3)	7 (31.8)	13 (29.5)
Hormone treatment	2 (9.1)	6 (27.3)	8 (18.2)
NSAID	2 (9.1)	1 (4.5)	3 (6.8)
Opioid	1 (4.5)	4 (18.2)	5 (11.4)
Sedative	1 (4.5)	1 (4.5)	2 (4.5)

Other	8 (36.4)	7 (31.8)	15 (34.1)
Signposted to IAPT	2 (9.1)	4 (18.2)	6 (13.6)
Depression/Anxiety	Mean (SD)	Mean (SD)	Mean (SD)
PHQ-9 (0-27)	8.14 (4.16)	10.41 (5.38)	9.27 (4.87)
GAD-7 (0-21)	7.23 (4.50)	8.50 (6.62)	7.91 (5.71)
	n (%)	n (%)	n (%)
PHQ-9 Moderate/Severe	7 (31.8)	14 (63.6)	21 (47.7)
GAD-7 Probable disorder	10 (45.5)	12 (54.5)	22 (50.0)

Note: PTSD = Post-Traumatic Stress Disorder; FND = Functional Neurological Disorder. Spinal disorder symptoms do not include osteoarthritis; Other comorbid conditions included anaemia, asthma, irritable bowel syndrome, long Covid-19, Ehlers-Danlos syndrome, tinnitus, dyslexia, glaucoma, psoriasis, and colitis. NSAID = non-steroidal anti-inflammatory drug; Other medication included proton-pump inhibitors, stimulants, selective serotonin receptor agonists (for migraine treatment), steroid treatment, anti-nausea medication. IAPT = Improving Access to Psychological Therapies - of those signposted to IAPT, 2 TAU participants were being treated, 1 TAU participant was waiting to be seen, 2 (1 ACT +TAU participant, 1 TAU participant) had been discharged and the status of 1 ACT +TAU participant was not reported. PHQ-9 = Patient Health Questionnaire-9 (Moderate/Severe = ≥10); GAD-7 = Generalized Anxiety Disorder-7 (Probable Anxiety Disorder = ≥8).

Table 2. Adjusted descriptive statistics and between-group effect size estimates for primary and secondary outcome measures (ITT approach).

	ACT +TAU	TAU	ACT +TAU versus TAU
	Mean (SE)	Mean (SE)	Effect size (95% CI)
Primary outcome			
AAQ-II (7-49)			
Baseline	21.50 (2.04)	20.86 (2.08)	
Post-Treatment	21.72 (2.52)	22.12 (2.53)	0.10 (-0.48,0.69)
Follow-up (16 weeks)	19.89 (2.07)	21.90 (2.15)	0.26 (-0.33,0.85)
Follow-up (26 weeks)	18.71 (2.24)	22.06 (2.29)	0.39 (-0.20,0.98)
Secondary outcomes			
<u>HRQoL/Functioning</u>			
WHODAS 2.0 Total (0-100)			
Baseline	34.31 (4.68)	39.67 (4.79)	
Post-Treatment	32.79 (4.73)	37.23 (4.86)	-0.05 (-0.64,0.54)
Follow-up (16 weeks)	32.65 (4.81)	37.45 (4.90)	0.07 (-0.52,0.66)
Follow-up (26 weeks)	31.27 (4.81)	41.92 (4.92)	0.30 (-0.29,0.89)
ICECAP (0-20)			
Baseline	13.46 (0.63)	13.19 (0.65)	
Post-Treatment	13.31 (0.65)	13.29 (0.68)	-0.08 (-0.67,0.50)
Follow-up (16 weeks)	13.30 (0.68)	13.09 (0.69)	-0.02 (-0.61,0.57)
Follow-up (26 weeks)	14.21 (0.68)	12.90 (0.69)	0.37 (-0.22,0.96)
EQ-5D-5L (Total value; -0.285 - 1.000)			
Baseline	0.725 (0.063)	0.703 (0.064)	
Post-Treatment	0.743 (0.064)	0.751 (0.066)	0.05 (-0.54,0.63)
Follow-up (16 weeks)	0.749 (0.066)	0.685 (0.067)	0.22 (-0.37,0.81)
Follow-up (26 weeks)	0.759 (0.066)	0.716 (0.068)	0.24 (-0.35,0.83)
EQ-VAS (0-100)			
Baseline	59.32 (4.79)	56.52 (4.89)	
Post-Treatment	63.43 (4.97)	56.75 (5.16)	0.17 (-0.42,0.76)
Follow-up (16 weeks)	67.35 (5.19)	52.66 (5.21)	0.52 (-0.08,1.12)
Follow-up (26 weeks)	67.15 (5.11)	54.95 (5.20)	0.41 (-0.18,1.01)
<u>Subjective cognitive symptoms</u>			
MMQ-Contentment (0-72)			
Baseline	21.36 (2.12)	16.86 (2.17)	
Post-Treatment	24.73 (2.38)	18.87 (2.49)	0.13 (-0.45,0.72)
Follow-up (16 weeks)	28.67 (2.36)	17.00 (2.40)	0.71 (0.10,1.31)
Follow-up (26 weeks)	28.28 (2.28)	18.22 (2.34)	0.55 (-0.05,1.15)
MMQ-Ability (0-80)			
Baseline	33.27 (3.51)	28.29 (3.60)	

Post-Treatment	33.16 (3.52)	27.80 (3.63)	0.02 (-0.56,0.61)
Follow-up (16 weeks)	36.02 (3.73)	28.10 (3.81)	0.18 (-0.41,0.76)
Follow-up (26 weeks)	33.84 (3.58)	28.62 (3.67)	0.01 (-0.57,0.60)
MMQ-Strategy (0-76)			
Baseline	37.86 (2.76)	39.57 (2.82)	
Post-Treatment	40.13 (3.02)	40.10 (3.15)	-0.13 (-0.72,0.46)
Follow-up (16 weeks)	39.69 (2.87)	40.67 (2.89)	-0.06 (-0.64,0.53)
Follow-up (26 weeks)	38.88 (2.43)	42.52 (2.48)	0.15 (-0.44,0.73)
<u>Depression / Anxiety</u>			
PHQ-9 (0-27)			
Baseline	8.55 (1.17)	9.29 (1.19)	
Post-Treatment	8.18 (1.21)	10.13 (1.25)	0.23 (-0.36,0.82)
Follow-up (16 weeks)	7.98 (1.24)	10.79 (1.26)	0.40 (-0.20,0.99)
Follow-up (26 weeks)	7.54 (1.24)	10.74 (1.26)	0.47 (-0.12,1.07)
GAD-7 (0-21)			
Baseline	7.59 (1.17)	5.38 (1.20)	
Post-Treatment	5.31 (1.20)	6.50 (1.25)	0.63 (0.03,1.23)
Follow-up (16 weeks)	6.03 (1.16)	6.76 (1.19)	0.55 (-0.05,1.15)
Follow-up (26 weeks)	6.35 (1.19)	7.58 (1.22)	0.64 (0.04,1.24)

Note: AAQ-II = Acceptance and Action Questionnaire; HRQoL = Health-related quality of life; WHODAS 2.0 = WHO Disability Assessment Schedule version 2.0. WHODAS 2.0 mean (SD) values were calculated using complex scoring, based on item response theory-based scoring (which accounts for multiple levels of difficulty for each WHODAS item; Üstün, 2010): ICECAP = Investigating Choice Experiments Capability Measure for Adults; EQ-5D-5L = EQ-5D-5L health state evaluation; EQ-VAS = current overall health rating (today); MMQ = Multifactorial Memory Questionnaire; PHQ-9 = Patient Health Questionnaire-9 ; GAD-7 = Generalized Anxiety Disorder-7. Effect sizes = Hedge's *g*; Positive effect sizes represent an improvement in symptoms (for MMQ-Strategy improvement was considered as reduced strategy use given the negative correlation between strategy use and memory satisfaction/ability). Effect sizes for WHODAS 2.0, EQ-5D-5L Total value score and MMQ-Strategy were calculated using transformed data; raw (adjusted) mean data are shown.

Table 3. Clinical Global Impression Scale scores at 6-month follow-up.

	ACT +TAU n = 15 Mean (SD)	TAU n = 15 Mean (SD)
Perceived change in condition from beginning to now (1-7)	3.33 (1.11)	4.73 (0.96)
	n (%)	n (%)
Very much improved	0 (0.0)	0 (0.0)
Much improved	3 (20.0)	0 (0.0)
Minimally improved	7 (46.7)	1 (6.7)
No change	3 (20.0)	6 (40.0)
Minimally worse	1 (6.7)	4 (26.7)
Much worse	1 (6.7)	4 (26.7)
Very much worse	0 (0.0)	0 (0.0)
<ins>Collapsed</ins>		
Good outcome	10 (66.7)	1 (6.7)

Note: A rating of 'improved' or 'much improved' perceived change in condition was considered a 'good outcome'.

Table 4. Adjusted means (SEs) and between-group effect sizes for 'per-protocol' participants completing measures at 2-, 4- and 6-month follow-ups.

	Baseline		Follow-up (2 months)			Follow-up (4 months)			Follow-up (6 months)		
	ACT (n=18)	TAU (n=21)	ACT (n=15)	TAU (n=16)	ACT vs TAU	ACT (n=12)	TAU (n=15)	ACT vs TAU	ACT (n=12)	TAU (n=15)	ACT vs TAU
	Mean (SE)	Mean (SE)	Mean (SE)	Mean (SE)	Effect Size (95% CI)	Mean (SE)	Mean (SE)	Effect Size (95% CI)	Mean (SE)	Mean (SE)	Effect Size (95% CI)
Primary outcome											
AAQ-II (7-49)	20.17 (1.99)	20.86 (2.29)	20.50 (1.80)	22.41 (1.74)	0.20 (-0.40,0.78)	15.88 (2.93)	21.42 (2.50)	0.57 (-0.03,1.17)	17.74 (2.07)	22.34 (1.85)	0.39 (-0.20,0.98)
Secondary outcomes											
WHODAS 2.0 (0-100)	31.90 (5.18)	39.66 (3.88)	35.05 (4.37)	35.01 (3.57)	0.03 (-0.56,0.61)	34.98 (5.79)	35.82 (3.58)	0.18 (-0.41,0.77)	35.19 (5.97)	38.72 (3.72)	0.28 (-0.31,0.87)
ICECAP (5-20)	13.61 (0.64)	13.19 (0.60)	13.47 (0.42)	13.31 (0.41)	0.05 (-0.54,0.63)	13.17 (0.73)	13.21 (0.63)	-0.01 (-0.60,0.58)	14.38 (0.48)	12.89 (0.43)	0.48 (-0.11,1.08)
EQ-VAS (0-100)	59.17 (5.70)	56.52 (4.96)	62.31 (3.77)	55.71 (3.65)	0.28 (-0.31,0.87)	66.23 (6.33)	52.37 (5.61)	0.52 (-0.08,1.11)	65.03 (5.88)	55.25 (5.13)	0.38 (-0.22,0.97)
EQ-5D-5L (-0.285 - 1.000)	0.763 (0.068)	0.703 (0.066)	0.721 (0.064)	0.746 (0.048)	0.07 (-0.52,0.66)	0.733 (0.068)	0.663 (0.074)	0.28 (-0.31,0.87)	0.717 (0.078)	0.746 (0.059)	0.10 (-0.49,0.69)
MMQ-Contentment (0-72)	22.61 (2.20)	16.86 (2.25)	24.67 (2.88)	20.40 (2.47)	0.39 (-0.20,0.98)	28.00 (3.57)	16.20 (1.84)	1.20 (0.56,1.84)	26.25 (2.99)	18.13 (1.92)	0.85 (0.23,1.46)
MMQ-Ability (0-80)	36.11 (3.86)	28.29 (3.28)	33.54 (3.55)	31.18 (2.72)	0.15 (-0.44,0.74)	36.71 (4.41)	28.81 (3.09)	0.46 (-0.13,1.06)	33.35 (3.96)	31.39 (3.05)	0.11 (-0.48,0.70)
MMQ-Strategy (0-76)	34.28 (2.19)	39.57 (2.87)	37.70 (2.38)	37.79 (2.31)	-0.004 (-0.59,0.58)	40.11 (2.90)	39.32 (2.48)	-0.08 (-0.66,0.51)	37.54 (32.06)	41.37 (1.84)	0.34 (-0.26,0.93)
PHQ-9 (0-27)	8.00 (1.06)	9.29 (1.15)	8.25 (1.00)	10.14 (0.97)	0.35 (-0.25,0.94)	7.78 (1.27)	11.05 (1.05)	0.60 (-0.002,1.20)	7.36 (1.39)	10.45 (1.33)	0.56 (-0.03,1.16)
GAD-7 (0-21)	7.00 (1.16)	5.38 (1.12)	4.16 (0.93)	7.17 (1.23)	0.57 (-0.03,1.17)	3.51 (0.89)	7.33 (1.31)	0.68 (0.08,1.29)	4.13 (0.92)	8.10 (1.23)	0.76 (0.15,1.37)

Note. ACT = ACT (plus TAU); SE = standard error; AAQ-II = Acceptance and Action Questionnaire; WHODAS 2.0 = WHO Disability Assessment Schedule version 2.0; ICECAP = Investigating Choice Experiments Capability Measure for Adults; EQ-5D-5L = EQ-5D-5L health state evaluation; EQ-VAS = current overall health rating (today); MMQ = Multifactorial Memory Questionnaire; PHQ-9 = Patient Health Questionnaire-9; GAD-7 = Generalized Anxiety Disorder-7. Effect sizes = Hedge's *g*; Positive effect sizes

represent an improvement in symptoms (for MMQ-Strategy improvement was considered as reduced strategy use given the negative correlation between strategy use and memory satisfaction/ability). Effect sizes for WHODAS 2.0, EQ-5D-5L Total value score and MMQ-Strategy were calculated using transformed data; raw (adjusted) mean data are shown.

Table 5. FCD care satisfaction

	ACT +TAU n = 14 Mean (SD)	TAU n = 15 Mean (SD)
<u>Satisfaction with overall care received for FCD (1-5)</u>	3.79 (0.89)	2.40 (0.63)
	n (%)	n (%)
Very Unsatisfied	0 (0.0)	1 (6.7)
Unsatisfied	1 (7.1)	7 (46.7)
Neutral	4 (28.6)	7 (46.7)
Satisfied	6 (42.9)	0 (0.0)
Very Satisfied	3 (21.4)	0 (0.0)
<u>Collapsed</u>		
Satisfied/Very satisfied	9 (64.3)	0 (0.0)

Table 6. Service use over follow-up, mean (SD), % using at least once by randomised group

Service (unit)	ACT + TAU (n=14)			TAU (n=14)		
	Mean	(SD)	%	Mean	SD	%
Employment						
Full time (months)	2.14	(2.98)	36	2.14	(2.85)	43
Part-time (months)	1.71	(2.81)	29	0.57	(1.60)	21
Unemployed (months)	1.29	(2.55)	21	1.71	(2.81)	29
Education/training (months)	0.57	(1.65)	14	0.43	(1.60)	7
Absent due to ill health (days)	15.86	(35.76)	50	22.21	(40.63)	50
Primary healthcare						
GP (number)	1.79	(1.85)	79	3.21	(3.72)	79
Practice nurse (number)	0.29	(0.61)	21	0.29	(0.61)	21
Community mental health team (number)	0.57	(1.65)	14	0.29	(0.73)	14
Psychologist/counsellor (number)	0.21	(0.58)	14	5.86	(16.16)	36
Physiotherapist/OT/SLT (number)	0.43	(1.60)	7	1.50	(3.28)	36
NHS 111 (number)	0.00	(0.00)	0	0.29	(0.61)	21
Secondary healthcare						
Inpatient stay (nights)	0.00	(0.00)	0	0.00	(0.00)	0
A&E (attendances)	0.00	(0.00)	0	0.00	(0.00)	0
Ambulance (call outs)	0.00	(0.00)	0	0.00	(0.00)	0
Diagnostic tests (number)	0.29	(0.61)	21	1.64	(3.10)	57
Outpatient appointments (number)	0.29	(0.61)	21	2.21	(3.51)	50
Medication						
Antidepressant			14			43
Sleeping tablet			21			0
Anti-anxiety			14			14
Mood stabiliser			7			0
ADHD medication			0			0

Table 7. Total cost (£) at baseline and follow-up, mean (SD) by randomised group

	ACT+TAU (n=14)		TAU (n=14)	
	Mean	(SD)	Mean	(SD)
BASELINE				
Primary healthcare	373.71	(566.78)	686.25	(1026.33)
Secondary healthcare	314.86	(403.43)	699.43	(749.09)
Medication	5.71	(0.56)	5.86	(0.48)
Total cost health & social care	**694.29**	**(683.80)**	**1391.53**	**(1417.15)**
Productivity losses	73.32	(54.49)	66.52	(55.44)
Total societal cost	**766.60**	**(667.02)**	**1458.05**	**(1407.91)**
FOLLOW-UP				
Intervention	238.33	(0.00)	0.00	(0.00)
Primary healthcare	264.51	(530.16)	583.15	(914.03)
Secondary healthcare	21.39	(52.03)	338.70	(555.74)
Medication	5.71	(0.47)	5.43	(1.60)
Total cost health & social care	**529.95**	**(522.84)**	**927.28**	**(1084.08)**
Productivity losses	67.64	(54.55)	61.61	(57.15)
Total societal cost	**597.59**	**(503.23)**	**988.89**	**(1084.79)**

Table 8. EQ-5D-5L utility score, QALYs, mean (SD)

	ACT+TAU		TAU	
	Mean	(SD)	Mean	(SD)
EQ-5D-5L VAS baseline (n=43)	59.318	22.076	56.524	22.728
EQ-5D-5L VAS follow-up (n=29)	65.929	27.280	52.800	24.063
EQ-5D-5L utility baseline (n=43)	0.657	0.315	0.652	0.292
EQ-5D-5L utility follow-up (n=29)	0.645	0.358	0.607	0.375
QALY over follow-up (n=29)	0.314	0.179	0.321	0.163

Adverse events

There were no adverse events associated with this study.