

Table 1 – Participant characteristics

		Intervention n= 279	Comparison n= 281	Total: n= 560
<b>Demographic characteristics</b>				
<b>Age (years)</b>	Mean(SD)	58.8 (5.2)	59.5 (5.7)	59.1 (5.4)
<b>SIMD quintile (%)</b>	1 (most deprived)	21 (7.5)	15 (5.3)	36 (6.4)
	2	25 (9.0)	29 (10.3)	54 (9.6)
	3	38 (13.6)	39 (13.9)	77 (13.8)
	4	65 (23.3)	60 (21.4)	125 (22.3)
	5 (least deprived)	128 (45.9)	135 (48.0)	263 (47.0)
	Unknown	2 (0.7)	3 (1.1)	5 (0.9)
<b>Ethnicity (%)</b>	<i>White, British</i>	<b>265 (95.0%)</b>	<b>265 (94.3%)</b>	<b>547 (94.6%)</b>
	<i>White, Irish</i>	<b>4 (1.4%)</b>	<b>1 (0.4%)</b>	<b>5 (0.9%)</b>
	<i>White, other</i>	<b>4 (1.4%)</b>	<b>8 (2.8%)</b>	<b>12 (2.1%)</b>
	<i>Mixed</i>	<b>0 (0%)</b>	<b>2 (0.7%)</b>	<b>2 (0.4%)</b>
	<i>Asian Indian</i>	<b>1 (0.4%)</b>	<b>1 (0.4%)</b>	<b>2 (0.4%)</b>
	<i>Asian, Pakistani</i>	<b>2 (0.7%)</b>	<b>0 (0%)</b>	<b>2 (0.4%)</b>
	<i>Asian, Chinese</i>	<b>1 (0.4%)</b>	<b>0 (0%)</b>	<b>1 (0.2%)</b>
	<i>Asian, other</i>	<b>2 (0.7%)</b>	<b>1 (0.4%)</b>	<b>3 (0.5%)</b>
	<i>Other</i>	<b>0 (0%)</b>	<b>2 (0.7%)</b>	<b>2 (0.4%)</b>
	Do not wish to complete	0 (0%)	1 (0.4%)	1 (0.2%)
<b>Education, highest level (%)</b>	Secondary	57 (20.4)	62 (22.1)	119 (21.3)
	Other professional/technical qualification	90 (32.3)	84 (29.9)	174 (31.1)
	University degree	132 (47.3)	135 (48.0)	267 (47.7)
<b>Employment (%)</b>	Retired	90 (32.3)	98 (34.9)	188 (33.6)
	Unemployed	2 (0.7)	7 (2.5)	9 (1.6)
	Employed full-time	91 (32.6)	90 (32.0)	181 (32.3)
	Employed part-time	71 (25.4)	65 (23.1)	136 (24.3)
	Student full-time	2 (0.7)	0 (0.0)	2 (0.4)
	Student part-time	0 (0.0)	1 (0.4)	1 (0.2)
	Other (please specify)	23 (8.2)	20 (7.1)	43 (7.7)
<b>Home status (%)</b>	Owner occupied	255 (91.4)	257 (91.5)	512 (91.4)
	Rented	24 (8.6)	24 (8.5)	48 (8.6)

**Table 2 - Changes in Body Weight and associated variables**

	Intervention Group			Comparison group			Between group difference; P value			
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	Unadjusted mean (95% CI)	P value	Adjusted for all SAP variables (95% CI)	P value
<b>Changes in anthropometric measures</b>										
<b>Measured body weight (kg)</b>										
Baseline	278	80.9 (13.3)		281	81.9 (12.8)					
12 months	226	77.8 (12.6)		240	80.2 (12.7)					
Difference to baseline	225	-2.5 (4.4)	-3.1 to -1.9	240	-1.2 (5.0)	-1.8 to -0.6	-1.59 (-3.17 to -0.01)	0.048	-1.29 (-2.15 to -0.43)	0.003
<b>Self-reported body weight (kg)</b>										
Baseline	267	79.4 (12.9)		272	80.4 (12.7)					
12 weeks	253	78.0 (12.4)		228	79.9 (13.5)					
Difference to baseline	245	-1.5 (3.3)	-1.9 to -1.1	224	-0.7 (3.4)	-1.2 to -0.3				
12 months	219	76.9 (12.7)		224	78.9 (12.7)					
Difference to baseline	210	-2.1 (4.8)	-2.8 to -1.5	219	-0.9 (5.5)	-1.6 to -0.1	-1.37 (-2.97 to 0.23)	0.092	-1.23 (-2.20 to -0.25)	0.014
<b>Mean waist circumference (cm)</b>										
Baseline	279	98.1 (12.5)		281	98.7 (11.7)					
12 months	226	95.5 (11.7)		239	97.4 (12.0)					
Difference to baseline	226	-2.3 (6.0)	-3.1 to -1.5	239	-1.0 (6.6)	-1.8 to -0.2	-1.20 (-2.67 to 0.28)	0.110	-1.24 (-2.38 to -0.10)	0.033
<b>BMI (measured)*</b>										
Baseline	279	31.0 (4.7)		281	31.3 (4.3)					
12 months	226	29.9 (4.6)		240	30.6 (4.3)					
Difference to baseline	226	-1.0 (1.6)	-1.2 to -0.7	240	-0.5 (1.9)	-0.7 to -0.2	0.98 (0.97 to 0.10)	0.048	0.98 (0.97 to 0.99)	0.002
<b>Percent weight loss at 12 months**</b>										
≥5% n (%)	279	76 (27.2%)		281	46 (16.4%)		Odds ratio 2.15 (1.41 to 3.29)	<0.001	Odds ratio 2.20 (1.41 to 3.43)	<0.001

\*log transformed (data presented as back transformations)    \*\* logistic regression allowing for close co-linearity (binary variables)

**Table 3 – Changes in physical activity measures**

Baseline and follow up measures										
	Intervention Group			Comparison group			Between group difference; P value			
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	Unadjusted mean (95% CI)	p-value	Adjusted for all SAP variables (95% CI)	p-value
<b>Changes in physical activity measures</b>										
<b>Number of steps/day (Activpal)</b>										
Baseline	59	9723 (3677)		66	9182 (3404)					
12 months	42	9444 (3800)		47	8548 (3160)					
Difference to baseline	36	-69.3(3019)	-952 to 1091	44	-435 (2104)	-1074 to 205	689 (-257 to 1634)	0.153	483 (-635 to 1602)	0.393
<b>Self-reported mins of physical activity/week *</b>										
Baseline	279	882 (783)		280	879 (676)					
12 weeks	262	964 (605)		264	921 (630)					
Difference to baseline	262	90 (679)	7 to 172	263	43 (598)	-30 to 115				
12 months	227	1046 (754)		239	906 (538)					
Difference to baseline	227	180 (617)	99 to 261	238	45 (660)	-39 to 129	1.1 (0.9 to 1.2)	0.316	1.1 (1.0 to 1.3)	0.123
<b>Sitting Time (min)</b>										
Baseline	59	1052.4 (97.5)		66	1048.4 (89.8)					
12 months	42	1050.9 (109.7)		47	1054.5 (97.5)					
Difference to baseline	36	0.1 (105.2)	-34.4. to 34.7	44	13.0 (81.5)	-11.8 to 34.7	0.8 (-25.5 to 27.1)	0.953	-12.9 (-52.6 to 26.9)	0.522

\*log transformed

**Table 3a – Changes in physical activity (curtailed to 360 mins/day)**

Baseline and follow up measures										
	Intervention group			Comparison group			Between group difference; P value			
	N	Mean (SD)	95%	N	Mean (SD)	95%	Unadjusted mean (95% CI)	p-value	Adjusted for all SAP variables (95% CI)	p-value
<b>Self-reported mins of physical activity/week (curtailed to 360 mins/day)</b>										
<b>Baseline</b>	279	841(574)	773 to 908	280	856 (581)	787 to 924				
<b>12 months</b>	227	1009 (610)	929 to 1084	239	901(523)	835 to 968				
<b>Difference to baseline</b>	227	178.3	104.9 to 251.7	238	60.9	-12.3 to 134.1	39.4 (-31.2 to 109.9)	0.274	119.6 (17.1 to 222.0)	0.022

**Table 4 – Changes in key health behaviours**

Baseline and follow up measures										
	Intervention Group			Comparison group			Between group difference; P value			
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	Unadjusted mean (95% CI)	p-value	Adjusted for all SAP variables (95% CI)	p-value
<b>Alcohol use (Audit-C score)**</b>										
Baseline	279	4.5 (2.75)		281	4.2 (2.56)					
12 months	227	3.9 (2.57)		240	3.8 (2.50)					
Difference to baseline	227	-0.5 (1.55)	-0.74 to -0.34	240	-0.4 (1.59)	-0.55 to -0.15	0.22 (-0.11 to 0.54)	0.197	0.13 (-0.49 to 0.75)	0.681
<b>Total fruit and vegetables (portions/day)</b>										
Baseline	279	5.1 (2.11)		281	5.1 (2.44)					
12 weeks	262	6.0 (2.06)		264	5.8 (2.66)					
Difference to baseline	262	0.9 (1.77)	0.64 to 1.07	264	0.6 (2.01)					
12 months	227	6.1 (2.20)		240	5.8 (2.47)					
Difference to baseline	227	0.9 (1.85)	0.70 to 1.18	240	0.6 (1.90)	0.39 to 0.88	0.17 (-0.11 to 0.46)	0.234	0.30 (-0.04 to 0.64)	0.080

\*\*Gamma distribution with identity link

**Table 5 - Changes in Reported lifestyle changes**

Baseline and follow up measures										
	Intervention Group		Comparison group		Between group difference; P value					
	N	N (%)	N	Mean (SD)	OR Unadjusted (95% CI)	p-value	OR Adjusted for baseline (95% CI)	p-value	OR Adjusted for all SAP variables (95% CI)	p-value
<b>Attempted to lose weight**</b>										
<b>Baseline</b>	279	245 (88%)	281	265 (94%)						
<b>12 months</b>	227	102(45%)	240	165(69%)						
<b>Difference to baseline</b>					0.46 (0.34 to 0.62)	<0.0001	0.40 (0.28 to 0.58)	0.667	0.98 (0.40 to 2.43)	0.618
<b>Attempted to increase physical activity**</b>										
<b>Baseline</b>	279	250 (90%)	281	255 (91%)						
<b>12 months</b>	227	212 (93%)	240	166(69%)						
<b>Difference to baseline</b>					2.49 (1.71 to 3.64)	<0.0001	2.35 (1.57 to 3.53)	<0.0001	2.48 (0.81 to 7.56)	<0.0001
<b>Attempted to reduce alcohol intake**</b>										
<b>Baseline</b>	279	82 (29%)	281	89(32%)						
<b>12 months</b>	227	90(40%)	240	66 (28%)						
<b>Difference to baseline</b>					1.22 (0.94 to 1.58)	0.145	1.25 (0.96 to 1.63)	0.015	1.51 (0.78 to 2.94)	0.012

\*\* logistic regression on binary variables for SAP variables except number of visits (close co-linearity with intervention allocation)

**Table 6 – Changes in key quality of life outcomes**

Baseline and follow up measures										
	Intervention Group			Comparison group			Between group difference; P value			
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	Unadjusted mean (95% CI)	p-value	Adjusted for all SAP variables (95% CI)	p-value
<b>EQ5D Health Index Score ***</b>										
Baseline	279	0.9 (0.14)		281	0.9 (0.15)					
12 weeks	262	0.9 (0.14)		264	0.9 (0.16)					
Difference to baseline	262	0.0 (0.13)	0.00 to 0.04	264	0.0 (0.15)	-0.01 to 0.03				
12 months	227	0.8 (0.18)		240	0.8 (0.17)					
Difference to baseline	227	-0.0 (0.15)	-0.03 to 0.02	240	-0.01 (0.14)	-0.03 to 0.01	0.00 (-0.02 to 0.02)	0.990	0.01 (-0.04 to 0.05)	0.726
<b>EQ5D Health state today</b>										
Baseline	279	75.2 (16.75)		281	75.2 (15.41)					
12 weeks	262	80.9 (13.68)		264	80.2 (14.87)					
Difference to baseline	262	5.4 (13.81)	3.73 to 7.09	264	5.3 (13.16)	3.67 to 6.86				
12 months	227	80.7 (13.87)		240	78.5 (15.16)					
Difference to baseline	227	5.0 (15.71)	2.98 to 7.09	240	2.5 (14.14)	0.70 to 4.29	5.45 (1.81 to 9.10)	0.004	0.57 (-4.60 to 5.75)	0.827

\*\*\*Gamma distribution with identity link

Table 7 Changes in key cardiovascular measures

Baseline and follow up measures										
	Intervention Group			Comparison group			Between group difference; P value			
	N	Mean (SD)	95% CI	N	Mean (SD)	95% CI	Unadjusted mean (95% CI)	P value	Adjusted for all SAP variables (95% CI)	P value
<b>HbA1C mmol/mol</b>										
Baseline	256	39.11 (6.70)		272	38.88 (5.46)					
12 months	200	39.70 (7.37)		220	39.20 (6.32)					
Difference to baseline <i>transformed</i>	199	0.46 (3.77)	-0.07 to 0.98	220	0.19 (2.49)	-0.14 to 0.52	1.01 (0.99 to 1.02)	0.510	1.01 (1.0 to 1.02)	0.241
<b>Insulin uU/ml</b>										
Baseline	256	22.41 (29.42)		272	20.54 (25.56)					
12 months	203	17.16 (19.00)		221	20.89 (26.86)					
Difference to baseline <i>transformed</i>	202	-4.86 (23.95)	-8.18 to -1.53	221	0.36 (34.82)	-4.25 to 4.98	0.95 (0.85 to 1.07)	0.405	0.84 (0.71 to 1.01)	0.057
<b>Total cholesterol mmol/L*</b>										
Baseline	256	5.10 (0.98)		272	5.03 (0.90)					
12 months	203	5.04 (0.96)		221	5.07 (0.95)					
Difference to baseline <i>transformed</i>	202	-0.05 (0.74)	-0.16 to 0.05	221	0.09 (0.57)	0.01 to 0.16	1.00 (0.98 to 1.03)	0.752	0.98 (0.95 to 1.00)	0.072
<b>HDL cholesterol mmol/L*</b>										
Baseline	256	1.34 (0.31)		272	1.36 (0.34)					
12 months	203	1.35 (0.31)		221	1.39 (0.35)					
Difference to baseline <i>transformed</i>	202	0.01 (0.19)	-0.02 to 0.04	221	0.02 (0.17)	-0.00 to 0.04	0.98 (0.95 to 1.01)	0.267	0.99 (0.97 to 1.02)	0.541
<b>Triglycerides mmol/L*</b>										
Baseline	256	1.52 (0.70)		272	1.46 (0.75)					
12 months	203	1.47 (0.70)		221		1.39 to 1.61				
Difference to baseline <i>transformed</i>	202	-0.04 (0.66)	-0.13 to 0.06	221	0.03 (0.57)	-0.04 to 0.11	1.03 (0.98 to 1.09)	0.280	0.96 (0.90 to 1.03)	0.265
<b>Mean Systolic blood pressure mmHg*</b>										
Baseline	279	129.76 (16.22)		280	131.93 (16.18)					
12 months	226	129.35 (16.82)		238	131.29 (16.96)					
Difference to baseline <i>transformed</i>	226	-0.61 (13.06)	-2.32 to 1.10	237	-0.59 (14.87)	-2.50 to 1.31	0.98 (0.97 to 1.00)	0.039	1.00 (0.98 to 1.02)	0.976
<b>Mean Diastolic blood pressure mmHg*</b>										
Baseline	279	80.14 (10.45)		280	80.94 (10.33)					
12 months	226	79.74 (10.10)		238	80.13 (9.81)	78.87 to 81.38				
Difference to baseline <i>transformed</i>	226	-0.36 (8.14)	-1.42 to 0.71	237	-0.44 (8.78)	-1.57 to 0.68	0.99 (0.98 to 1.01)	0.318	1.00 (0.98 to 1.02)	0.888

\*log transformed



**Table 8 - Serious Adverse Events Summary**

	<b>Intervention</b>	<b>Comparison</b>	<b>Total</b>
All participants	279	281	560
Participants without serious adverse events	278	278	556
All adverse events	98	114	212
All serious adverse events	2	4	6
Cerebrovascular accident	0 (0.0%)	1 (0.9%)	1 (0.5%)
Coronary artery disease	1 (1.0%)	0 (0.0%)	1 (0.5%)
Fall	0 (0.0%)	1 (0.9%)	1 (0.5%)
Myocardial infarction	1 (1.0%)	0 (1.0%)	1 (0.5%)
Pulmonary embolism	0 (0.0%)	1 (0.9%)	1 (0.5%)
Urosepsis	0 (0.0%)	1 (0.0%)	1 (0.5%)

**Table 9** Adjusted<sup>2</sup> mean incremental costs, incremental QALYs, and incremental cost-effectiveness ratio over 12 months between intervention group vs usual care group from NHS perspective

Analysis	Incremental mean costs, £ (95% CI) <sup>3,4,5</sup>	Incremental mean QALYs (95% CI) <sup>3,4,5</sup>	ICER (£/QALY)
Complete cases <sup>6</sup>	541.74 (429.71 to 656.68)	0.006 (-0.015 to 0.029)	83,440
SA: Decrease time spent to 50% by staff on intervention-related activities (complete case)	500.72 (388.85 to 615.17)	0.006 (-0.015 to 0.029)	77,123
SA: Increase time spent to 70% by staff on intervention-related activities (complete case)	582.68 (470.66 to 698.07)	0.006 (-0.015 to 0.029)	89,746
SA: Lower intervention cost (complete cases) <sup>7</sup>	358.74 (247.92 to 471.38)	0.006 (-0.015 to 0.029)	55,255
SA: Imputed dataset	548.94 (447.10 to 649.20)	0.006 (-0.012 to 0.022)	99,804
<p><b>Notes</b></p> <p>2 Adjusted for baseline differences (age, Scottish Index of Multiple Deprivation, employment status, smoking status, body mass index, alcohol intake, eating habits, physical activity time, baseline EQ-5D health utility score and baseline cost).</p> <p>3 Bootstrapped non-parametric 95% confidence interval (2.5<sup>th</sup>/97.5<sup>th</sup> percentile).</p> <p>4 Generalised linear model with Poisson distribution and power 0.5 link function to estimate incremental costs and generalised linear model with Gaussian distribution and identity link function to estimate incremental QALYs (complete cases).</p> <p>5 Discounted at 3.5% per year.</p> <p>6 Included intervention cost of £505 per participant. This consists of staff cost, lifestyle coaches training cost and ActWELL delivery cost. Based on the activities performed from Jan 2017 to Dec 2019, 60% staff time was spent on coach recruitment, training, support and management.</p> <p>7 Included intervention cost of £326 per participant. This considers costs that would accrue when ActWELL programme is rolled out in 'real life' and in steady state. Staff cost (1-year salary of all staffs), training cost and ActWELL delivery cost were included.</p> <p><b>Abbreviations</b></p> <p>QALYs, quality-adjusted life-years; ICER, incremental cost-effectiveness ratio; SA, sensitivity analysis.</p>			

**Table 10 - Breakdown of intervention costs per participant**

Category	Component	Primary analysis	SA #1	SA #2	SA #3
Staff time	ActWELL Project Officer Salary	67,373	56,144	78,602	37,430
	Office Co-ordinator (equivalent salary £22,000 pa)	5,192	5,192	5,192	5,192
	Management Cost	30,288	30,288	30,288	10,500
	Hays - Temp recruitment	8,250	8,250	8,250	8,250
	Communications officer time (equivalent salary £32, 500 pa) 16 days	2,000	2,000	2,000	2,000
Staff training	ActWELL Project Officer Training & Associated costs	1,040	1,040	1,040	1,040
Staff travel	ActWELL Project Officer travel costs for meetings related to ActWELL (TMG and leisure centres)	741	741	741	741
	ActWELL Project Officer Travel costs for volunteer support	1,439	1,439	1,439	1,439
Ad cost	Facebook paid for ads	250	250	250	250
Office supplies	ActWELL office supplies: Locking boxes for storing personal data, resources for events	189	189	189	189
	ActWELL Postage for ActWELL packs and returning mobile phones	181	181	181	-
Coach training	Venue	-	-	-	-
	Accommodation	2,943	2,943	2,943	2,943
	Catering	2,815	2,815	2,815	2,815
	Trainer:				
	A	2,433	2,433	2,433	2,433
	B	1,265	1,265	1,265	1,265
	C	999	999	999	999
	Coach pack	1,642	1,642	1,642	1,642
Delivery to participants	Mobile phone costs - coaches, equivalent annual cost at 3.5% per annum	1,965	1,965	1,965	1,965
	Travel expenses - coaches (intervention visits)	5,631	5,631	5,631	5,631
	Participant pack - production costs	4,342	4,342	4,342	4,342

Total cost	Sum of staff time, staff training, staff travel, ad cost, office supplies, coach training, delivery to participants	140,978	129,749	152,207	91,065
<b>Cost per participant (£)</b>	<b>N=279</b>	<b>505</b>	<b>465</b>	<b>546</b>	<b>326</b>

Primary analysis: 60% time spent by project officer on intervention, Jan 2017-Dec 2019.

Sensitivity Analysis 1 (SA#1): 50% time spent by project officer on intervention, Jan 2017-Dec 2019.

Sensitivity Analysis 2 (SA#2): 70% time spent by project officer on intervention, Jan 2017-Dec 2019.

Sensitivity Analysis 3 (SA#3): Costs expected when ActWELL is rolled out and in steady state (assumes only annual salary for project officer and 18% on-costs).

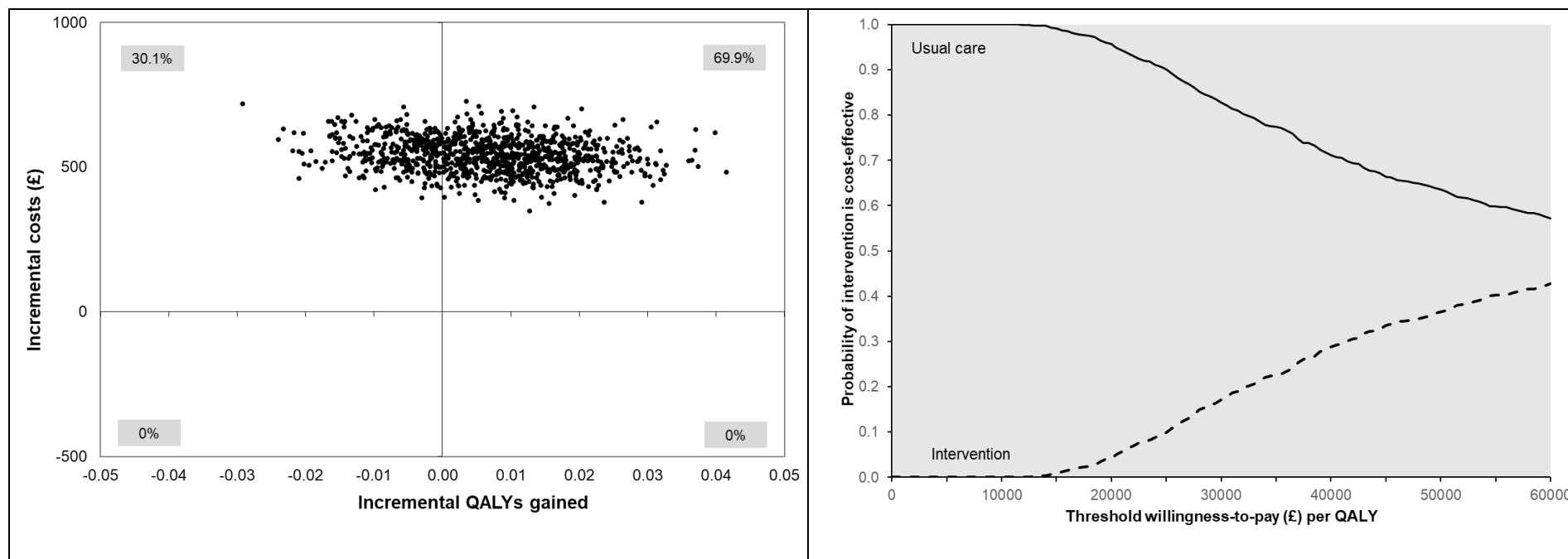
**Figure 1 – Assessment measures**

<b>OUTCOME MEASURES</b>				
<b>Primary Outcomes</b>		<b>Base line</b>	<b>12 week</b>	<b>12 month</b>
Body weight	Measured using digital body weight scales (kg)	X		X
Physical Activity	7 days accelerometry with activPAL (steps)	X		X
<b>Secondary outcomes</b>				
Modes of physical activity Sedentary behaviour	Scottish Physical Activity Questionnaire SPAQ <sup>34</sup>	X	X	X
	7 days accelerometry with activPAL™ (subsample only)	X		X
Anthropometric changes	BMI (height and weight) Waist circumference (cm)	X		X
Eating habits	Questionnaire based on Scottish Health Survey <sup>22</sup>	X		X
	Fruit and vegetable intake <sup>45</sup>		X	
Alcohol intake	Audit C questionnaire <sup>46</sup>	X		X
Psycho-social variables	Modified brief illness questionnaire <sup>47</sup>	X		X
	Knowledge and beliefs about lifestyle and breast cancer risk (developed in house)	X		X
	Psychosocial health measures resources (perceived motivation, awareness, ability, action, monitoring, and social support around weight management)			X
	Perceived body weight (developed in-house)	X	X	X
Economic outcomes	EQ5D-5L questionnaire <sup>42</sup>	X	X	X
	Economic health resource usage (Developed by HERU, University of Aberdeen)	X		X

**Figure 2 - Key components of the lifestyle coach sessions (face to face visits)**

Visit 1 – Face-to-face (60 minutes)	Visit 2 – Face-to-face (45 minutes)
<ul style="list-style-type: none"> <li>• identification of BMI</li> <li>• Instruct participant on pedometer use and proposed walking programme</li> <li>• Walk and talk 10 min (interactive walking session)</li> <li>• Physical activity goal setting (implementation intention setting and personalised walking programme)</li> <li>• Discuss how to reduce sedentary behaviour</li> <li>• Caloric value of (hot and cold) alcohol and sugary drinks discussed “Sugar Savvy” quiz undertaken (<a href="https://www.wcrf-uk.org/sites/default/files/are-you-sugar-savvy-game.pdf">https://www.wcrf-uk.org/sites/default/files/are-you-sugar-savvy-game.pdf</a>) (advice given on alternatives, portion size, frequency) (Possibility of implementation intention setting on drinks)</li> <li>• Weight loss goal (emphasis on modest up to 7% in 12 months)</li> <li>• Motivational interviewing questions on weight loss</li> <li>• Guidance on self-monitoring, weekly self-weighing, reporting and feedback– implementation intention setting for weighing</li> <li>• Initial dietary challenges – snacking and “weakness foods” (based on a verbal 24hour intake)</li> <li>• Summarise meeting – goal setting, action and coping planning, times of relapse</li> </ul>	<ul style="list-style-type: none"> <li>• Praise success (however modest)</li> <li>• Evaluate and modify PA goals as required. Check body weight recorded</li> <li>• Reminder about body weight and breast cancer risk reduction (even after 50)</li> <li>• Highlight weight loss principles (revising snacking, importance of meal patterns and 5 a day)</li> <li>• Remind about goal set for weight loss and how this converts to personal eating plan</li> <li>• Review 24hour diet recall sheets (handed out last visit) (or take a 24hour recall if sheets not completed) • Discuss calories – focus on -600kcal deficit diet (Identify personalised eating plan using British Heart Foundation (BHF) materials)</li> <li>• Discuss Portion sizes and frequencies (use images from BHF materials and portion distortion information)</li> <li>• Food labelling</li> <li>• Identify Implementation intentions on one food/drinking habit (set one only- if suggestions needed base on 24hour recordings)</li> <li>• Summarise goals and key challenges, check all materials provided</li> <li>• Arrange first two telephone appointments</li> <li>• Discuss leisure centre activity to meet staff (if interested)</li> </ul>
<b>Nine, follow-up phone calls</b>	
<ul style="list-style-type: none"> <li>• Check well being</li> <li>• Check goal progress, self-reported weight, re-enforce the importance of self-monitoring</li> <li>• Identify success and challenges</li> <li>• Discuss possible problems ahead (e.g. holidays)</li> <li>• Coping strategies and starting again if intentions failed</li> <li>• Start discussion on the importance of habits in eating behaviours using Ten Top Tips.</li> <li>• Weight Loss and Weight Loss Maintenance</li> <li>• Highlight the importance of regular food intake (including breakfast) and portion size Refer to Keep to your meal routine and Focus on Food</li> <li>• Stress the importance of physical activity and social support Refer to Tips Walk off the weight</li> <li>• Re-enforce importance of self-monitoring</li> <li>• Re-enforce information on snacking Refer to Pack a Healthy snack and Five a Day</li> <li>• Re-enforce information on drinks sweet and alcohol and value of water Refer to Think about your drinks</li> <li>• Re-evaluate portions size (as per BHF booklet) Refer to Caution with your portions</li> <li>• Return to discussing physical activity and reducing sedentary behaviour Refer to Up on your feet</li> <li>• Re-evaluation of goals, coping planning, where next, summarise success</li> </ul>	

**Figure 3 - Probability of cost-effectiveness, Primary analysis over 12 months, using complete cases (n=452)**



**Figure 4 - Summary of Mammographers' experience of the ActWELL study**

<b>Initial responses to the study proposal</b>	<ul style="list-style-type: none"> <li>In terms of response to the proposal of involving mammographers in study interest, the response was mixed. In one service, the staff team were excited to be involved in the study because they perceived this as a valuable opportunity for women which in turn may have a positive impact on attendance rates. In contrast, in another service, (one that had previously been involved in a pilot of the intervention), the champion described a reluctance on the part of colleagues to become involved again. However, she also remarked that this may simply have represented resistance to another change to routines.</li> </ul>
<b>Mammographers' perceptions of the study purpose</b>	<ul style="list-style-type: none"> <li>ActWELL champions understood and appreciated that the purpose of the study was to reduce women's risk of breast cancer by addressing lifestyle factors. As such there appeared to be no resistance from mammographers towards the study premise, yet one champion, had reservations about the way in which women were approached about the study, demonstrated concerns about discussing such an emotive topic as cancer risk and linking this with weight in what is a very brief clinical appointment.</li> </ul>
<b>Embedding ActWELL introduction into practice</b>	<ul style="list-style-type: none"> <li>Mammographers recognised that the key to implementing the ActWELL recruitment task was to make it part of the clinic practice routine and described ways in which this was achieved.</li> <li>Generally it was felt that, as the recruitment became embedded into practice, the impact on consultation times and overall smooth running of the service was manageable: <i>"once we established a pattern for it, it was actually more achievable than we initially thought"</i></li> <li>It was noted, however, that there was limited time to answer any questions which women might raise without impacting on the very tight appointment schedule. For one interviewee, the concern about lack of time was bound up with and reinforced the concerns expressed in another service about the inappropriateness of telling women about the link between unhealthy lifestyle and cancer risk.</li> </ul>
<b>Barriers and challenges</b>	<ul style="list-style-type: none"> <li>Generally, these were practical, with time pressures being most consistently identified as an issue which affected both staff and the women themselves: <i>"it did feel a bit rushed, and it wasn't fair on the ladies, but you can only do what you can with the time you are given"</i>.</li> </ul>
<b>Perceptions of women's response and information needs</b>	<ul style="list-style-type: none"> <li>Despite concerns expressed by one mammographer that women might feel it inappropriate to have the issue of lifestyle and cancer risk mentioned during mammography, no mammographers mentioned in the interviews any instances of women feeling distressed, although it should also be noted that the tight timing of appointments meant there was limited time for staff to gauge how women felt.</li> <li>No mammographers felt that including the ActWELL recruitment in the screening process had impacted negatively on women's willingness to attend for screening.</li> </ul>
<b>Modifications</b>	<ul style="list-style-type: none"> <li>In terms of suggested modifications to the recruitment process itself, these were generally minor in nature.</li> </ul>



**Figure 5 - Summary of Participants' views on the Actwell study (procedures and intervention)**

24 participants were interviewed by telephone using a semi-structured interview guide. The sample was selected to represent all study areas and a range of socio-economic backgrounds using SIMD.

<b>Views on the study and intervention</b>	
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>• Most women recalled finding out about the study through 'leaflets', 'cards' or 'posters' at the mammography clinic – only a minority recalled any conversation about it.</li> <li>• Study information materials were felt to have been clear and helpful. The only area of uncertainty was around the term 'lifestyle coach', which conjured up expectations for some of a more personalised, intensive form of support.</li> <li>• The mammography setting was felt to have been an appropriate recruitment channel</li> </ul>
<b>Motives for participation</b>	<ul style="list-style-type: none"> <li>• Motives for participation were both altruistic (to support worthwhile research, to help find out about preventing cancer) and self-help/improvement (particularly, to lose weight, and generally to improve health). Sometimes both types of motive were present, reinforcing each other. For some, Actwell had come along at a key moment (change of routine, big birthday, awareness of own mortality, family illness).</li> <li>• Breast cancer prevention was not necessarily a salient factor for many, and there was low awareness of BCN involvement.</li> </ul>
<b>Acceptability and convenience</b>	<ul style="list-style-type: none"> <li>• Research nurse appointments were felt to have been pleasant and well handled.</li> <li>• Venues for lifestyle coach meetings were mostly felt to have been appropriate, although some had found them difficult to get to, and the rooms available had not always been very pleasant.</li> <li>• Telephone calls were mostly felt to have been acceptable and convenient, and of appropriate frequency and duration.</li> <li>• Views on overall mix and timing of face-to-face meetings and telephone calls: mostly, participants felt this was about right, although some felt they would have welcomed more face-to-face support.</li> </ul>
<b>Views on the lifestyle coaches</b>	<ul style="list-style-type: none"> <li>• Generally coaches were highly regarded. Seen as pleasant, warm, positive, although one participant reacted negatively.</li> <li>• Usually coaches were perceived as empathetic, understanding, and non-judgemental, although some felt that 'slim' coaches did not necessarily understand the challenges faced by overweight women.</li> <li>• Generally praised for quality of support provided, with some coaches being described as having particular insight and skill in knowing how to motivate change.</li> <li>• Some interviewees had expected that coaches would have a background in lifestyle coaching or specialist knowledge (for example, concerning particular conditions and dietary needs). Some participants had not been aware at start that all coaches would be volunteers.</li> </ul>
<b>Views on the intervention</b>	<ul style="list-style-type: none"> <li>• Goal setting appeared generally to have worked well, with participants feeling they had been appropriately involved, and goals being perceived as realistic and manageable.</li> <li>• Varying views on the information and advice provided. In some cases, seen as not specific enough, or not telling participants anything new.</li> <li>• For some participants, the move to telephone calls was disappointing as they lacked the rapport and accountability associated with face-to-face contact. Others, however, felt the phone calls provided sufficient support and encouragement.</li> </ul>

	<ul style="list-style-type: none"> <li>Participants generally appreciated using the pedometers (although they were difficult to wear, compared with fitbit-type watches). There were more mixed views on regularly weighing themselves, with some finding it helpful and others demotivating.</li> </ul>
<b>Suggestions for changes and improvements to Actwell</b>	<p>Many felt 'nothing' needed changing, but some suggestions were offered:</p> <ul style="list-style-type: none"> <li>around a third would have welcomed more contact with lifestyle coach, either during or after the 12 month period.</li> <li>some suggested contact with other participants – 'buddy' system or an informal social group.</li> <li>some would have liked feedback on the blood tests at baseline and follow-up</li> </ul>
<b>Barriers and facilitators to change (analysed in relation to the COM-B model)</b>	
<b>Capability</b>	<ul style="list-style-type: none"> <li>Health (conditions which affected mobility, recent surgery), life events such as Christmas and holidays, and stressful periods, could reduce capability and make participants fall back into old patterns of treats and comfort eating.</li> </ul>
<b>Opportunity</b>	<ul style="list-style-type: none"> <li>Work (for those still in employment), family caring commitments and looking after pets could reduce time available for activity and affect energy and motivation, but could also present opportunities for exercise.</li> <li>Weather/lack of daylight and cost of accessing healthy food and leisure facilities were negative factors for some. Several commented on free activity options such as walking on beach.</li> </ul>
<b>Motivation</b>	<ul style="list-style-type: none"> <li>Could be both a positive and negative factor; some were strongly driven and self-motivated, others needed external boosts to motivation such as the regular contact with the coach. Personal goals, such as being fitter to play with grandchildren, were helpful.</li> <li>Mixed experiences of family and friend support.</li> </ul>

**Figure 6 - Summary of coaches' views on the Actwell training and intervention**

Eight coaches who met the following eligibility criteria undertook semi-structured interviews:

- had seen a minimum of three intervention participants
- represented the four areas participating in the ActWELL study
- represented the different waves of ActWELL training (four coaches from the first wave of training, two from each of the second and third waves of training).

<b>Background</b>	<ul style="list-style-type: none"> <li>• The coaches had a range of backgrounds and experiences, including nursing, general practice, fitness coaching, voluntary work, education and nutrition. Some were retired while others were in work, sometimes also juggling other family commitments. Some had prior experience of breast cancer, either themselves or among their family and friends.</li> </ul>
<b>Perceptions of study and role</b>	<ul style="list-style-type: none"> <li>• The coaches clearly understood the prevention concept at the heart of ActWELL, and perceived that the aim of the study was to assess whether a lifestyle coach approach could encourage lifestyle changes, specifically relating to physical activity, diet, alcohol use and weight.</li> <li>• Lifestyle coaches understood that the nature of their role was primarily “<i>support and encouragement</i>” for women to identify changes they could make for themselves, rather than to direct them to follow a particular plan of action.</li> </ul>
<b>Training</b>	<ul style="list-style-type: none"> <li>• Lifestyle coaches generally enjoyed and appreciated the training. For some with prior experience of this kind of work it was felt to be sufficient and appropriate. However, others noted the training to be intense and hurried for the amount of learning required. The use of role play elicited mixed responses.</li> </ul>
<b>Management of intervention procedures</b>	<ul style="list-style-type: none"> <li>• All coaches praised the support they had received from Breast Cancer Now (BCN). The manager in charge of ActWELL volunteers was described as helpful, supportive, quick to respond and efficient.</li> <li>• The process was generally described as well managed and straightforward, and coaches particularly appreciated that there was flexibility to accommodate their particular requirements and circumstances. The types of queries which lifestyle coaches received typically concerned health problems experienced by intervention participants and the implications of these for their involvement in the study. Generally, lifestyle coaches found the process of scheduling appointments to be manageable and not too onerous.</li> <li>• Some had found the paperwork (including record forms for intervention and research purposes) which they had to complete after each session and telephone call manageable and straightforward but other struggled.</li> <li>• The process of arranging meeting venues in local leisure centres was mostly straightforward, with leisure centre staff generally being described as helpful and accommodating, albeit centralised booking systems sometimes made it difficult to speak directly to the venue. However, some issues were experienced regarding room availability and suitability, particularly where the only space available was in a public area.</li> <li>• The process of scheduling and making telephone calls was generally experienced as unproblematic.</li> </ul>

	<ul style="list-style-type: none"> <li>• A consistent theme across the interviews was the duration of the face to face appointments, with coaches finding that the appointments, particularly the first one, could take much longer than had been recommended in the training. This was for two main reasons. Firstly, coaches found that it was important to build a rapport with the participant, and this took time. Secondly, the requirement in the first face to face appointment to take the participant for a 10 minute walk ate substantially more into the appointment time than anticipated.</li> <li>• Lifestyle coaches were very positive about their experience of volunteering on the ActWELL programme, including speaking of their enjoyment of being in contact with and supporting participants.</li> <li>• In terms of their routines, coaches were generally able to accommodate their ActWELL involvement, although it was acknowledged that the time commitment was substantial and in some cases had exceeded initial expectations. However, generally, lifestyle coaches noted that it was made clear to them that volunteering to be a coach would be a substantial time commitment, and those who were interviewed took this commitment seriously.</li> </ul>
<b>Participant interactions</b>	<ul style="list-style-type: none"> <li>• Overall, coaches felt a high level of confidence in carrying out their role, although some indicated nervousness and uncertainty in the initial stages. Opportunities to practise and gain experience were helpful for those who started with lower confidence but saw this grow over time.</li> <li>• Coaches noted a generally good level of engagement in ActWELL participants, with most starting off very enthusiastic. Over time, coaches found that engagement in participants varied, particularly after the face to face appointments came to an end and the intervention moved on to telephone support. In some cases the process had been straightforward, with participants continuing to respond well to the programme in this second phase; however, in other cases the transition to telephone calls had been somewhat unsatisfactory.</li> <li>• Another coach commented that most of their participants had lost a lot of weight before they had started on ActWELL, and so few lost further weight during the intervention.</li> <li>• Multiple barriers and facilitators to participants' progress within ActWELL were identified by coaches. Barriers reflected characteristics of participants' lifestyles and routines, including the role of food in their lives; as well as their approach to, and understanding of ActWELL. Facilitators to progress were identified within the ActWELL programme and in participants themselves including their levels of self-motivation, and interest in physical activity, healthier diets and good health generally.</li> <li>• Coaches had various suggestions for improving ActWELL and these focussed on the format and content of the programme and better supporting coaches to prepare for and deliver the intervention.</li> </ul>