Correction to Cost and Outcome of BehaviouRal Activation (COBRA): a randomised controlled trial of behavioural activation versus cognitive behavioural therapy for depression. *Health Technology Assessment* **Volume: 21, Issue: 46, Published in August 2017**

One of our collaborators has been preparing a paper for publication using data from the COBRA trial, during which we uncovered an error in the coding of one of the mediation variables from our process evaluation: the Snaith–Hamilton Pleasure Scale (SHAPS).

Although this was a minor part of our report, we have, therefore, corrected the raw data and repeated the descriptive analyses for SHAPS and all mediation analyses that included SHAPS.

We are pleased to report that the interpretation of the mediation analyses remains essentially the same when using the corrected SHAPS scores, meaning that there are no substantial changes required when interpreting the results section of our original report. Our findings remain that SHAPS was not a mediator of PHQ-9 in the single mediator models (SHAPS at 6m mediating the effect of intervention on PHQ-9 at 12m and 18m, and SHAPS at 12m mediating PHQ-9 at 18m), nor in the multiple mediator models (mediators at 6m mediating the effect of intervention on PHQ-9 at 12m and 18m). There remain no significant mediators of the intervention effect (the corrected SHAPS was not a significant mediator, and as in the published report, the other mediator variables were also non-significant).

Although our report's conclusions remain unchanged, with the publication of our colleague's paper likely, this document is the correction to the original COBRA report which includes the corrected descriptive data, analyses, and figures:

1. Text on P46 third and fourth paragraphs, amendments (deletions and replacements highlighted in yellow)
2. Table 18, p43: SHAPS descriptive data at baseline/6m/12m/18m
3. Table 20, p48-49: SHAPS at 6m as single mediator for PHQ9 at 12m; multiple mediator model (including SHAPS) with mediators at 6m mediating PHQ at 12m
4. Table 21 p50: SHAPS at 6m as single mediator for PHQ9 at 18m; multiple mediator model (including SHAPS) with mediators at 6m mediating PHQ at 12m; SHAPS at 12m mediating PHQ at 18m
5. Figure 17 p46: mean plot of SHAPS scores by group
6. Figure 22 p92: line plot of SHAPS scores by group
7. In addition, in reviewing the report again, we noticed that there was a typesetting error in Table 19. The error is that one of the columns in table 19 (p47) – column 6 – has been copied from column 5 rather than the actual data for column 6 being included. We have, therefore, included our original Table 19 again and highlighted the correct data.

David Richards, COBRA Trial Chief Investigator

P46 third and fourth paragraphs

For the overall treatment fidelity, the indirect effect of treatment group acting via this mediator was statistically significant (-0.18, 95% confidence ~~-0.54 to -0.01~~ 0.01 to 0.54), mediating -117% of the total treatment effect (Table 20). In the multiple mediator model, however, none of the mediators were found to have a significant indirect effect. BADS avoidance, BADS social impairment, total RRS score, ~~SHAPS, basic treatment fidelity,~~ and overall treatment fidelity, were found to mediate at least 10% in magnitude of the total treatment effect.

At 18-month follow-up, the indirect effect of treatment via basic treatment fidelity in the individual mediator model was statistically significant (observed effect 0.61, 95% CI 0.23 to 1.17) and associated with a proportion of total effect mediated of 610%. In the multiple mediators model, with mediator variables measured at 6-month follow-up, this effect was not statistically significant but was associated with a proportion of total effect mediated of ~~77~~61%. Similarly, the indirect effect via overall treatment quality was statistically significant (observed effect 0.24, 95% CI 0.03 to 0.65) in the individual mediator model, but this significant effect was not seen in the multiple mediators model.

TABLE 18 Unadjusted scores for PHQ-9 and mediator variables for mediation population
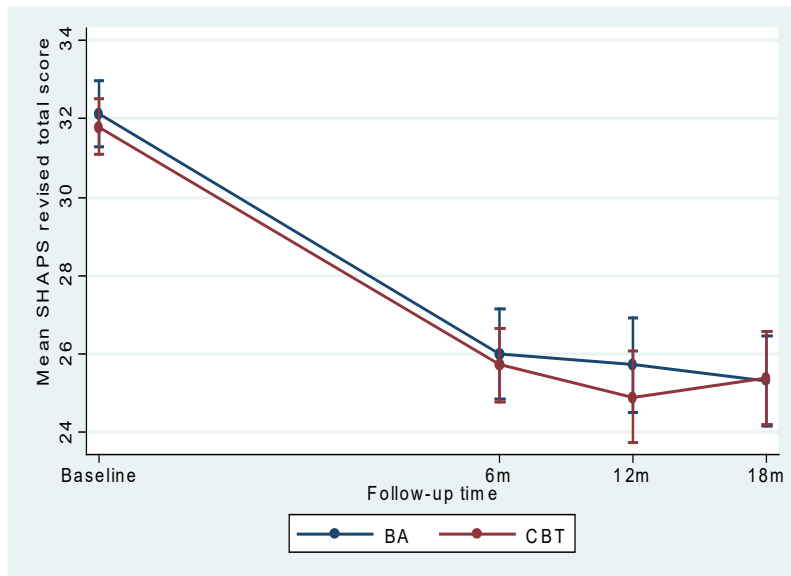
Outcome variable	Baseline		PM1		PM2		6-month follow-up		12-month follow-up		18-month follow-up	
	CBT	BA	CBT	BA	CBT	BA	CBT	BA	CBT	BA	CBT	BA
PHQ-9; mean (SD), n	17.39 (4.85), 214	17.69 (4.80), 219	DNC	DNC	DNC	DNC	9.41 (7.04), 190	9.72 (6.88), 183	8.20 (7.32), 184	8.34 (6.97), 173	8.39 (7.12), 176	8.32 (7.13), 174
BADS total; mean (SD), n	88.30 (19.98), 195	87.65 (21.32), 206	76.35 (24.46), 92	75.69 (27.10), 91	63.74 (27.76), 78	67.15 (27.56), 67	55.88 (29.65), 146	56.74 (30.18), 144	DNC	DNC	DNC	DNC
BADS activation; mean (SD), n	29.57 (7.21), 206	29.90 (7.67), 214	26.73 (7.86), 104	26.35 (7.97), 100	22.82 (8.28), 85	22.78 (9.48), 78	21.34 (9.24), 155	22.09 (9.90), 151	DNC	DNC	DNC	DNC
BADS avoidance; mean (SD), n	26.77 (9.47), 209	25.86 (9.31), 215	23.85 (10.54), 105	23.35 (10.03), 106	19.66 (10.14), 85	20.19 (9.39), 79	15.96 (11.25), 155	17.37 (10.72), 159	DNC	DNC	DNC	DNC
BADS work impairment; mean (SD), n	15.78 (6.24), 212	16.09 (6.43), 219	14.23 (6.38), 105	14.15 (6.97), 105	11.56 (7.20), 85	11.30 (6.07), 81	10.09 (7.08), 157	9.98 (6.99), 160	DNC	DNC	DNC	DNC

BADS social impairment; mean (SD), n	15.81 (7.23), 205	16.13 (7.77), 211	11.91 (7.53), 101	13.45 (8.39), 101	10.25 (8.14), 84	11.28 (8.27), 74	8.63 (8.02), 156	8.75 (8.06), 154	DNC	DNC	DNC	DNC
DAS; mean (SD), n	154.23 (38.35), 211	152.02 (38.67), 217	158.36 (40.04), 109	158.72 (40.65), 107	150.71 (41.98), 88	152.70 (41.38), 84	134.66 (41.95), 159	135.97 (42.15), 160	DNC	DNC	DNC	DNC
RRS total; mean (SD), n	60.28 (10.05), 213	59.61 (11.18), 219	58.29 (11.59), 109	58.18 (12.42), 111	52.22 (12.28), 88	53.45 (13.53), 85	48.27 (14.48), 159	49.95 (14.24), 160	DNC	DNC	DNC	DNC
RRS reflection; mean (SD), n	12.30 (3.12), 213	12.05 (3.41), 219	12.06 (2.99), 109	11.86 (3.35), 111	11.03 (3.00), 88	11.04 (3.59), 85	10.38 (3.44), 159	10.58 (3.37), 160	DNC	DNC	DNC	DNC
SHAPS; mean (SD), n	31.80 (5.33), 212	32.14 (6.35), 217	DNC	DNC	DNC	DNC	25.74 (6.01), 161	26.01 (7.29), 161	24.92 (7.48), 163	25.74 (7.39), 147	25.39 (7.67), 161	25.33 (7.21), 155
Proportion (%) of sessions attended (of a maximum of 24)[a]; mean (SD), n									52 (33), 214	48 (33), 219		

Basic treatment fidelity (scale 0–100)[a]; mean (SD), n								73 (31), 213	86 (28), 218	
Overall treatment fidelity (scale 0–100)[a]; mean (SD), n								68 (31), 213	73 (33), 218	

[a]Treatment fidelity outcomes measured across the full follow-up period, reported under 12-month follow-up for convenience.

DNC: Data not collected; DNR: Data not reported.

FIGURE 17 SHAPS total score at baseline, 6-, 12- and 18-month follow-up by treatment group for the mediation population.

TABLE 19 Results of structural equation modelling analyses for mediation of treatment effect on PHQ-9 at 6-month follow-up

	Single mediator models			Model including all mediators	
Mediator	Indirect effect of treatment allocation acting through mediator (95% CI), n	Total effect of treatment allocation (95% CI)	Proportion of total effect mediated by indirect effect (%)	Indirect effect of treatment allocation acting through mediator (95% CI), n	Proportion of total effect mediated by indirect effect (%)[a]
Mediators measured at PM 1 (therapy session 4)					
				Total effect of treatment allocation -1.84 (95% CI -3.79 to 0.04), n=158	
BADS total	0.18 (-0.34 to 0.91), 163	-1.52 (-3.43 to 0.34)	-12	Not included	Not included
BADS activation	0.12 (-0.51 to 0.75), 186	-1.52 (-3.45 to 0.32)	-8	0.13 (-0.11 to 0.81)	-7
BADS avoidance	0.11 (-0.17 to 0.71), 195	-1.34 (-3.14 to 0.51)	-8	-0.01 (-0.38 to 0.18)	0
BADS work impairment	0.10 (-0.45 to 0.69), 198	-1.45 (-3.24 to 0.42)	-7	0.05 (-0.10 to 0.65)	-3
BADS social impairment	-0.06 (-0.50 to 0.32), 184	-1.54 (-3.43 to 0.18)	4	0.04 (-0.12 to 0.52)	-2
DAS	0.13 (-0.26 to 0.71), 202	-1.73 (-3.46 to 0.16)	-8	0.18 (-0.12 to 0.84)	-10
RRS total	0.13 (-0.31 to 0.63), 206	-1.64 (-3.40 to 0.18)	-8	0.06 (-0.14 to 0.64)	-3
RRS reflection	0.04 (-0.09 to 0.39), 206	-1.60 (-3.36 to 0.21)	-2	Not included	Not included
Mediators measured at PM 2 (therapy session 7)					
				Total effect of treatment allocation -2.63 (95% CI -4.87 to -0.32), n=126	

BADS total	-0.23 (-1.45 to 0.89), 129	-2.52 (-4.94 to -0.35)	9	Not included	Not included
BADS activation	0.21 (-0.57 to 1.15), 153	-1.68 (-3.67 to 0.37)	-13	-0.01 (-0.47 to 0.19)	1
BADS avoidance	-0.05 (-0.84 to 0.72), 154	-2.26 (-4.42 to -0.12)	2	-0.01 (-0.48 to 0.30)	0
BADS work impairment	0.34 (-0.64 to 1.38), 160	-2.01 (-4.05 to -0.01)	-17	0.04 (-0.35 to 0.80)	-1
BADS social impairment	-0.29 (-1.29 to 0.56), 147	-2.33 (-4.46 to -0.23)	13	-0.19 (-1.19 to 0.19)	7
DAS	0.23 (-0.54 to 0.93), 166	-1.95 (-3.95 to 0.20)	-12	0.10 (-0.16 to 0.84)	-4
RRS total	-0.02 (-0.77 to 0.68), 167	-2.00 (-4.07 to -0.02)	1	-0.04 (-0.59 to 0.24)	2
RRS reflection	0.11 (-0.42 to 0.71), 167	-2.04 (-4.06 to -0.02)	-5	Not included	Not included

[a]Proportions of total effect mediated are not required to sum to 100%

TABLE 20 Results of structural equation modelling analyses for mediation of treatment effect on PHQ-9 at 12-month follow-up

	Single mediator models			Model including all mediators	
Mediator	**Indirect effect of treatment allocation acting through mediator (95% CI), n**	**Total effect of treatment allocation (95% CI)**	**Proportion of total effect mediated by indirect effect (%)**	**Indirect effect of treatment allocation acting through mediator (95% CI), n**	**Proportion of total effect mediated by indirect effect (%)[a]**
Mediators measured at PM 1					
				Total effect of treatment allocation - 0.58 (95% CI -2.61 to 1.59), n=154	
BADS total	0.09 (-0.78 to 0.81), 158	-0.49 (-2.55 to 1.41)	-18	Not included	Not included
BADS activation	0.01 (-0.69 to 0.61), 181	-0.79 (-2.74 to 1.09)	-1	0.08 (-0.27 to 0.69)	-14
BADS avoidance	0.02 (-0.47 to -0.49), 189	-0.82 (-2.76 to 1.14)	-3	0.01 (-0.20 to 0.45)	-3
BADS work impairment	0.03 (-0.69 to 0.61), 192	-0.56 (-2.51 to 1.35)	-5	0.08 (-0.26 to 0.79)	-15
BADS social impairment	-0.16 (-0.80 to 0.23), 179	-0.78 (-2.71 to 1.18)	21	0.00 (-0.24 to 0.24)	0
DAS	0.08 (-0.15 to 0.61), 198	-0.93 (-2.84 to 0.92)	-9	-0.18 (-0.90 to 0.13)	32
RRS total	0.09 (-0.41 to 0.66), 201	-0.98 (-2.88 to 0.83)	-9	0.10 (-0.09 to 0.73)	-17
RRS reflection	0.08 (-0.17 to 0.54), 201	-0.95 (-2.84 to 0.87)	-9	Not included	Not included
Mediators measured at PM 2					
				Total effect of treatment allocation -0.84 (95% CI -3.23 to 1.58), n=125	

BADS total	-0.29 (-1.40 to 0.64), 128	-0.53 (-2.98 to 1.74)	55	Not included	Not included
BADS activation	-0.09 (-0.73 to 0.84), 150	-0.27 (-2.29 to 1.69)	-33	-0.04 (-0.72 to 0.14)	5
BADS avoidance	-0.10 (-0.74 to 0.48), 150	-0.37 (-2.36 to 1.66)	26	0.00 (-0.38 to 0.52)	-1
BADS work impairment	0.14 (-0.76 to 1.10), 156	-0.47 (-2.58 to 1.67)	-31	-0.03 (-0.91 to 0.78)	4
BADS social impairment	-0.33 (-1.35 to 0.43), 145	-0.58 (-2.78 to 1.52)	57	-0.20 (-1.51 to 0.15)	23
DAS	0.11 (-0.42 to 0.67), 162	-0.57 (-2.58 to 1.49)	-19	-0.04 (-0.73 to 0.21)	5
RRS total	0.01 (-0.67 to 0.71), 163	-0.68 (-2.71 to 1.32)	-2	-0.03 (-0.63 to 0.43)	4
RRS reflection	0.20 (-0.23 to 0.90), 163	-0.72 (-2.73 to 1.28)	-28	Not included	Not included
Mediators measured at 6-month follow-up					
				Total effect of treatment allocation 0.37 (-1.24 to 2.00) n=250	
BADS total	0.09 (-0.77 to 1.05), 258	0.27 (-1.33 to 1.93)	33	Not included	Not included
BADS activation	-0.05 (-0.82 to 0.68), 281	-0.22 (-1.73 to 1.31)	25	0.01 (-0.33 to 0.35)	1
BADS avoidance	-0.40 (-1.13 to 0.37), 285	-0.06 (-1.52 to 1.42)	720	-0.10 (-0.61 to 0.10)	-28
BADS work impairment	0.24 (-0.46 to 1.04), 294	-0.26 (-1.82 to 1.17)	-94	0.03 (-0.10 to 0.42)	7
BADS social impairment	0.26 (-0.52 to 1.09), 282	-0.06 (-1.58 to 1.53)	-463	0.07 (-0.12 to 0.58)	19
DAS	0.08 (-0.80 to 0.61), 296	-0.26 (-1.72 to 1.26)	33	-0.02 (-0.36 to 0.12)	-4
RRS total	-0.31 (-0.99 to 0.41), 297	-0.30 (-1.82 to 1.16)	105	-0.11 (-0.57 to 0.21)	-31
RRS reflection	-0.14 (-0.68 to 0.40), 297	-0.30 (-1.81 to 1.17)	47	Not included	Not included

SHAPS	-0.12 (-0.65 to 0.44), 298	-0.12 (-1.64 to 1.38)	103	0.02 (-0.07 to 0.34)	6
Treatment fidelity mediators[b]					
Proportion of sessions attended	-0.04 (-0.28 to 0.04), 350	-0.14 (-1.49 to 1.30)	29	0.00 (-0.19 to 0.16)	0
Basic treatment fidelity	0.33 (-0.03 to 0.83), 349	-0.15 (-1.55 to 1.27)	-216	0.01 (-0.87 to 0.69)	2
Overall treatment fidelity	0.18 (0.01 to 0.54), 349	-0.15 (-1.55 to 1.27)	-117	0.08 (-0.37 to 0.75)	21

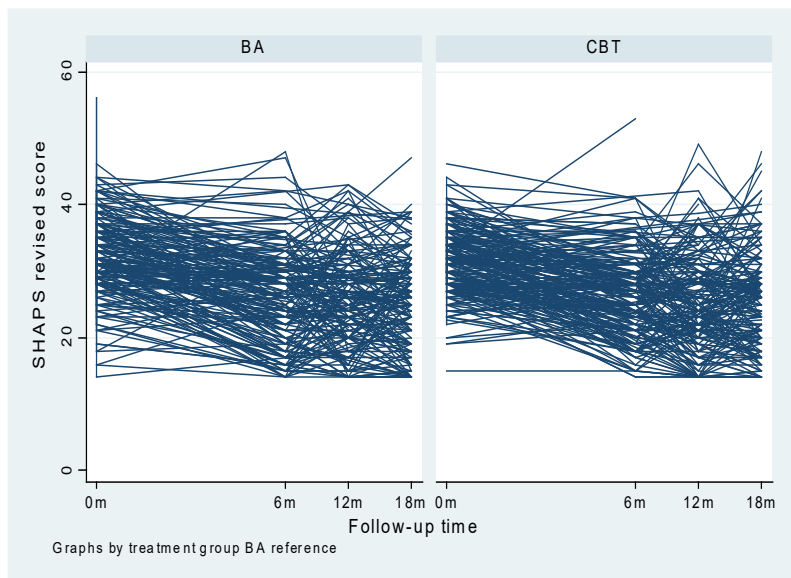[a]Proportions of total effect mediated are not required to sum to 100%.

[b] Treatment fidelity mediators included in model with mediators measured at 6-month follow-up.

TABLE 21 Results of structural equation modelling analyses for mediation of treatment effect on PHQ-9 at 18-month follow-up

	Single mediator models			Model including all mediators	
Mediator	Indirect effect of treatment allocation acting through mediator (95% CI), n	Total effect of treatment allocation (95% CI)	Proportion of total effect mediated by indirect effect (%)	Indirect effect of treatment allocation acting through mediator (95% CI), n	Proportion of total effect mediated by indirect effect (%)
Mediators measured at 6-month follow-up					
				Total effect of treatment allocation 0.55 (-1.05 to 2.08), n=248	
BADS total	0.06 (-0.76 to 0.96), 255	0.64 (-0.91 to 2.27)	9	Not included	Not included
BADS activation	-0.10 (-0.81 to 0.60), 278	0.14 (-1.42 to 1.64)	-75	0.00 (-0.17 to 0.27)	1
BADS avoidance	-0.38 (-1.05 to 0.25), 283	0.19 (-1.32 to 1.69)	-196	0.02 (-0.13 to 0.41)	3
BADS work impairment	0.17 (-0.52 to 0.90), 291	0.03 (-1.47 to 1.49)	653	0.11 (-0.08 to 0.64)	20
BADS social impairment	0.25 (-0.47 to 1.11), 278	0.56 (-0.88 to 2.14)	45	0.13 (-0.30 to 0.76)	24
DAS	-0.02 (-0.63 to 0.64), 294	0.03 (-1.44 to 1.52)	-76	0.00 (-0.22 to 0.22)	0
RRS total	-0.31 (-0.93 to 0.32), 294	0.02 (-1.43 to 1.49)	-1600	-0.06 (-0.42 to 0.07)	-11
RRS reflection	-0.09 (-0.51 to 0.35), 294	0.03 (-1.44 to 1.50)	-357	Not included	Not included
SHAPS	-0.03 (-059 to 0.53), 293	-0.03 (-1.52 to 1.49)	111	0.01 (-0.10 to 0.32)	2
Treatment fidelity mediators[a]					

Proportion of sessions attended	-0.04 (-0.28 to 0.04), 343	0.12 (-1.29 to 1.53)	-36	0.03 (-0.09 to 0.44)	6
Basic treatment fidelity	0.61 (0.23 to 1.17), 342	0.10 (-1.28 to 1.54)	610	0.33 (-0.47 to 1.17)	61
Overall treatment fidelity	0.24 (0.03 to 0.65), 342	0.10 (-1.28 to 1.54)	237	-0.02 (-0.61 to 0.54)	-4
Mediators measured at 12-month follow-up					
SHAPS	-0.39 (-1.26 to 0.40), 291	0.33 (-1.18 to 1.92)	-119	Not included	Not included

[a] Treatment fidelity mediators included in model with mediators measured at 6-month follow-up.

FIGURE 22 Individual participant SHAPS scores at baseline, 6-, 12-, and 18-month follow-up for each treatment group for the mediation population.