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Section: Disposition
Figure 1 Recruitment curve
Population: Full (n = 15)

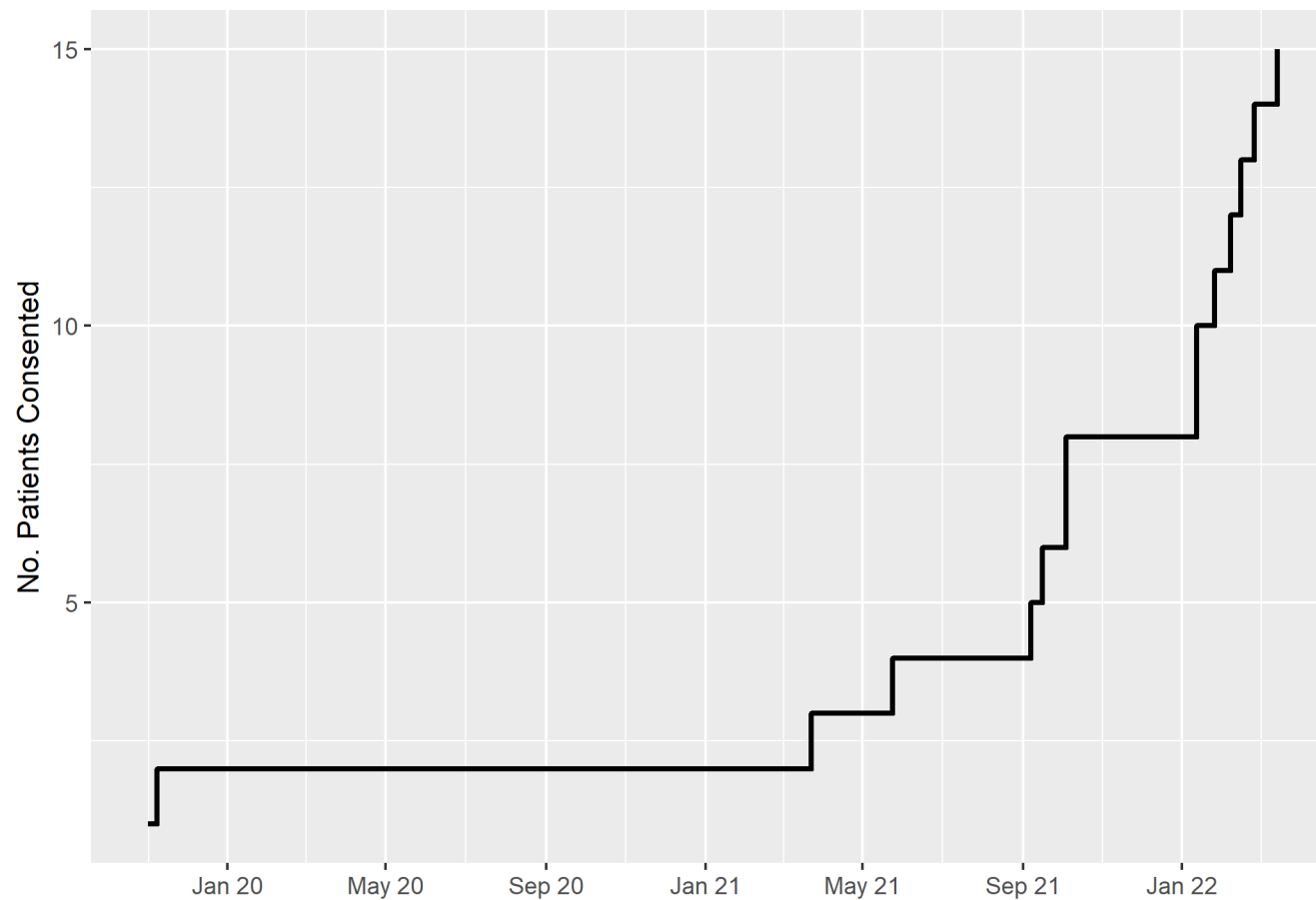


Table 1 Recruitment
Population: Full (n = 15)

Group	N01 - Cambridgeshire and Peterborough NHS Foundation Trust & University of Cambridge	N03 - King's College London	N04 - Oxford Health NHS Foundation Trust	N06 - Cardiff and Vale University Health Board	Total
Placebo	3	2	0	1	6
Active	2	3	1	3	9
Total	5	5	1	4	15

Table 2Populations	
Population: Full (n = 15)	
Group	n
Subjects in MACRO	15
Enrolled Population (consented)	15
Safety Population (eligible)	15
Randomised Population	15
Full Population	15

Table 3Group allocation
Population: Full (n = 15)

Participant ID	Group	Site	Site Name	Country	Screening	Visit 1	Visit 2	Visit 3	Follow-up
10004	Active	N01	Cambridgeshire and Peterborough NHS Foundation Trust & University of Cambridge	United Kingdom	2019-11-01	2019-11-20	2019-11-20	2019-12-19	2020-01-24
10006	Placebo	N01	Cambridgeshire and Peterborough NHS Foundation Trust & University of Cambridge	United Kingdom	2019-11-08	2019-12-04	2019-12-19	NA	NA
10019	Placebo	N01	Cambridgeshire and Peterborough NHS Foundation Trust & University of Cambridge	United Kingdom	2021-03-23	2021-06-03	2021-07-01	2021-08-02	2021-08-13
10036	Active	N01	Cambridgeshire and Peterborough NHS Foundation Trust & University of Cambridge	United Kingdom	2022-02-07	2022-03-16	2022-04-13	2022-05-10	2022-05-20
10038	Placebo	N01	Cambridgeshire and Peterborough NHS Foundation Trust & University of Cambridge	United Kingdom	2022-02-15	2022-03-22	2022-04-19	2022-05-19	2022-05-27
30002	Active	N03	King's College London	United Kingdom	2021-05-24	2021-06-21	2021-07-22	2021-08-16	2021-08-25
30006	Placebo	N03	King's College London	United Kingdom	2021-09-16	2021-10-19	2021-11-16	2021-12-13	2022-01-20
30011	Placebo	N03	King's College London	United Kingdom	2022-01-12	2022-02-22	2022-03-23	2022-04-21	2022-04-29
30013	Active	N03	King's College London	United Kingdom	2022-01-26	2022-03-02	2022-03-30	2022-04-25	2022-05-04
30015	Active	N03	King's College London	United Kingdom	2022-03-15	2022-04-04	2022-04-27	2022-05-30	2022-06-10
40005	Active	N04	Oxford Health NHS Foundation Trust	United Kingdom	2022-01-12	2022-02-14	2022-03-17	2022-04-11	2022-04-19
60004	Placebo	N06	Cardiff and Vale University Health Board	United Kingdom	2021-09-07	2021-10-12	2021-11-08	2021-12-06	2021-12-14
60009	Active	N06	Cardiff and Vale University Health Board	United Kingdom	2021-10-04	2021-11-09	2021-12-10	2022-01-05	2022-01-18
60010	Active	N06	Cardiff and Vale University Health Board	United Kingdom	2021-10-04	2022-02-15	2022-03-15	2022-04-12	2022-04-22
60014	Active	N06	Cardiff and Vale University Health Board	United Kingdom	2022-02-25	2022-03-28	2022-04-22	2022-05-24	2022-06-07

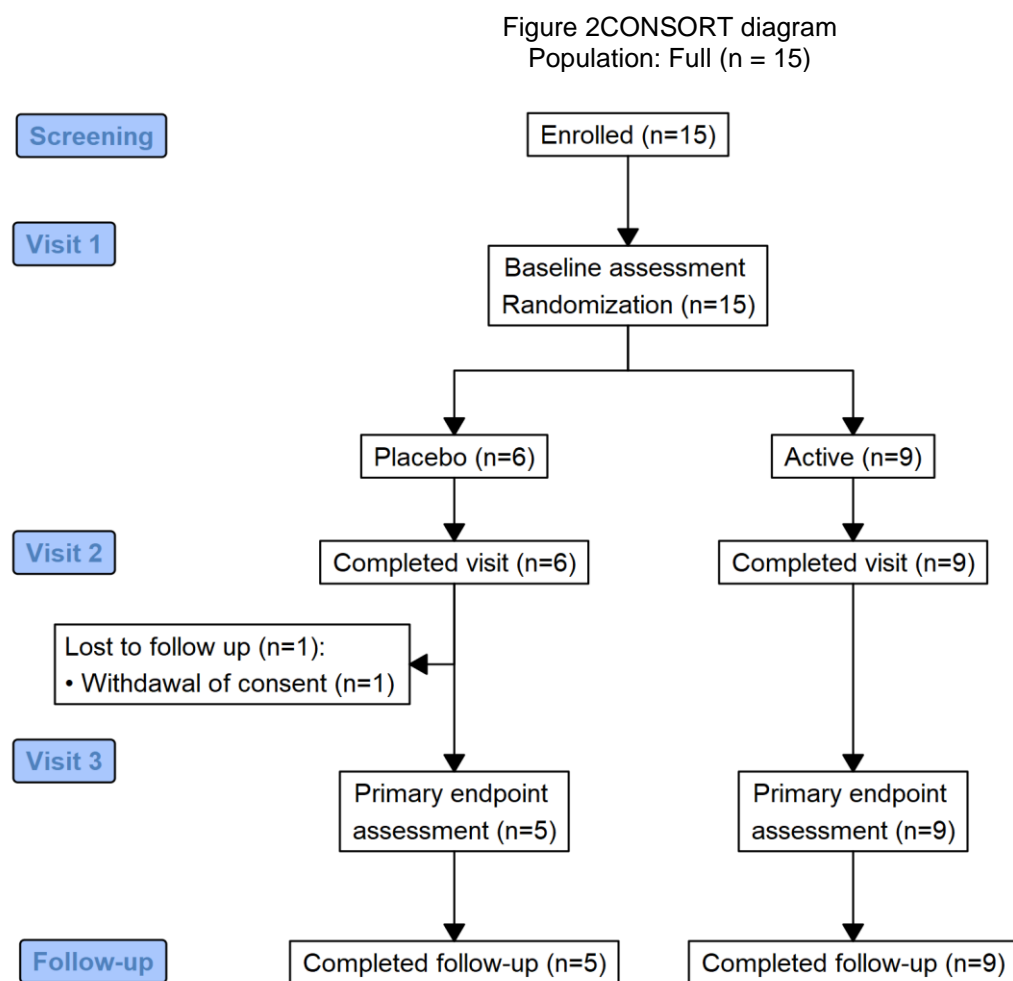


Table 4Withdrawals
Listing Population: Full (n = 15)

Participant ID	Group	Site	Date of early withdrawal	Primary reason for early withdrawal	Last scheduled visit completed while still on IMP
10006	Placebo	N01	2019-12-19	Participant withdrawal of consent from trial	D28 visit/ visit 2

Section: Baseline Characteristics
 Table 5Demographics
 Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
Sex			
Male	3/6 (50%)	1/9 (11%)	4/15 (27%)
Female	3/6 (50%)	8/9 (89%)	11/15 (73%)
Age (at screening)			
Valid Obs.	6	9	15
Mean (SD)	47.5 (14.8)	37.2 (13.6)	41.3 (14.5)
Median [Min, Max]	55.0 [22.0, 59.0]	31.0 [22.0, 56.0]	45.0 [22.0, 59.0]
Derived age			
Valid Obs.	6	9	15
Mean (SD)	47.5 (14.8)	37.2 (13.6)	41.3 (14.5)
Median [Min, Max]	55.0 [22.0, 59.0]	31.0 [22.0, 56.0]	45.0 [22.0, 59.0]
Ethnicity			
White	5/6 (83%)	8/9 (89%)	13/15 (87%)
Mixed	1/6 (17%)		1/15 (7%)
Asian		1/9 (11%)	1/15 (7%)
Marital_Status			
Single	3/6 (50%)	3/9 (33%)	6/15 (40%)
Divorced/widowed/separated	2/6 (33%)	2/9 (22%)	4/15 (27%)
Married/In a partnership	1/6 (17%)	4/9 (44%)	5/15 (33%)
Education			
Postgraduate	2/6 (33%)	2/9 (22%)	4/15 (27%)
College/University	1/6 (17%)	5/9 (56%)	6/15 (40%)
School	3/6 (50%)	2/9 (22%)	5/15 (33%)
Occupation			
Full time	4/6 (67%)	7/9 (78%)	11/15 (73%)
Part time	1/6 (17%)		1/15 (7%)
Not in paid employment	1/6 (17%)	2/9 (22%)	3/15 (20%)

Table 6 Physical measurements and examination
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
Weight			
Valid Obs.	6	9	15
Mean (SD)	89.2 (10.2)	84.2 (11.2)	86.2 (10.8)
Median [Min, Max]	87.9 [77.4, 107]	85.4 [66.2, 99.1]	85.8 [66.2, 107]
Height			
Valid Obs.	6	9	15
Mean (SD)	1.73 (0.0961)	1.65 (0.0736)	1.68 (0.0894)
Median [Min, Max]	1.73 [1.62, 1.89]	1.67 [1.50, 1.75]	1.68 [1.50, 1.89]
BMI			
Valid Obs.	6	9	15
Mean (SD)	29.7 (1.97)	30.8 (3.14)	30.4 (2.71)
Median [Min, Max]	29.7 [27.2, 33.0]	30.5 [24.5, 35.1]	30.0 [24.5, 35.1]
Derived BMI			
Valid Obs.	6	9	15
Mean (SD)	29.8 (1.98)	30.8 (3.14)	30.4 (2.71)
Median [Min, Max]	29.7 [27.2, 33.0]	30.6 [24.5, 35.1]	30.0 [24.5, 35.1]

Section: Baseline Medical Assessments
Table 7 Recreational drugs and alcohol test
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
Result of drugs test			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Result of alcohol breath test			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Visit = Visit 1			
Observation	6	9	15
Result of drugs test			
Positive		1/9 (11%)	1/15 (7%)
Negative	6/6 (100%)	8/9 (89%)	14/15 (93%)
Result of alcohol breath test			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Visit = Visit 2			
Observation	6	9	15
Result of drugs test			
Positive		1/8 (13%)	1/14 (7%)
Negative	6/6 (100%)	7/8 (88%)	13/14 (93%)
Missing		1 (11%)	1 (7%)
Result of alcohol breath test			
Missing	6 (100%)	9 (100%)	15 (100%)
Visit = Visit 3			
Observation	5	9	14
Result of drugs test			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Result of alcohol breath test			
Missing	5 (100%)	9 (100%)	14 (100%)
Visit = Follow-up			
Observation	2	3	5
Result of drugs test			
Missing	2 (100%)	3 (100%)	5 (100%)
Result of alcohol breath test			
Missing	2 (100%)	3 (100%)	5 (100%)

Table 8Pregnancy test
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
FSH levels			
Valid Obs.	0	1	1
Mean (SD)		118 (NA)	118 (NA)
Median [Min, Max]		118 [118, 118]	118 [118, 118]
Missing	6 (100%)	8 (89%)	14 (93%)
FSH Not Required			
Not Applicable	3/3 (100%)	7/7 (100%)	10/10 (100%)
Missing	3 (50%)	2 (22%)	5 (33%)
Pregnancy test result			
Negative	3/6 (50%)	7/9 (78%)	10/15 (67%)
Not applicable, Male	3/6 (50%)	1/9 (11%)	4/15 (27%)
Not applicable, Sterilised		1/9 (11%)	1/15 (7%)
HsCRP test result			
No	5/6 (83%)	9/9 (100%)	14/15 (93%)
Yes	1/6 (17%)		1/15 (7%)
Estimated GFR result			
Valid Obs.	6	9	15
Mean (SD)	96.6 (6.33)	97.9 (17.4)	97.4 (13.7)
Median [Min, Max]	95.3 [89.7, 108]	96.6 [68.0, 122]	96.5 [68.0, 122]
Results outside of normal range			
No	1/6 (17%)	1/9 (11%)	2/15 (13%)
Yes	5/6 (83%)	8/9 (89%)	13/15 (87%)
Genotype rs3751143 (1513 A>C)			
A/A	2/5 (40%)	7/8 (88%)	9/13 (69%)
C/A	3/5 (60%)	1/8 (13%)	4/13 (31%)
Missing	1 (17%)	1 (11%)	2 (13%)
Genotype rs1653624 (1729 T>A)			
T/T	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing	1 (17%)	1 (11%)	2 (13%)
C/A or A/A genotype at rs3751143 AND T/T genotype			
Yes, participant is eligible	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing	1 (17%)	1 (11%)	2 (13%)

Table 9Supine ECG
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
Result of ECG			
Normal	3/6 (50%)	8/9 (89%)	11/15 (73%)
Abnormal NOT Clinically Significant	3/6 (50%)	1/9 (11%)	4/15 (27%)
Does participant show LBBB			
Valid Obs.	0	0	0
Missing	6 (100%)	9 (100%)	15 (100%)
ECG QT Interval Measure 1			
Valid Obs.	6	9	15
Mean (SD)	406 (25.0)	400 (27.5)	402 (25.8)
Median [Min, Max]	415 [364, 430]	400 [358, 440]	404 [358, 440]
ECG QT Interval Measure 2			
Valid Obs.	6	8	14
Mean (SD)	408 (22.4)	403 (25.0)	405 (23.1)
Median [Min, Max]	417 [372, 428]	411 [366, 438]	414 [366, 438]
Missing		1 (11%)	1 (7%)
ECG QT Interval Measure 3			
Valid Obs.	6	8	14
Mean (SD)	405 (21.1)	401 (24.2)	403 (22.2)
Median [Min, Max]	413 [372, 424]	406 [366, 440]	409 [366, 440]
Missing		1 (11%)	1 (7%)
ECG QT Average Measurement			
Valid Obs.	6	8	14
Mean (SD)	406 (23.0)	401 (25.6)	403 (23.7)
Median [Min, Max]	415 [369, 427]	409 [364, 439]	411 [364, 439]
Missing		1 (11%)	1 (7%)
DB Derived ECG QT Average Measurement			
Valid Obs.	6	8	14
Mean (SD)	406 (23.0)	401 (25.6)	403 (23.7)
Median [Min, Max]	415 [369, 427]	409 [364, 439]	411 [364, 439]
Missing		1 (11%)	1 (7%)
ECG QTcFridericia measurement 1			
Valid Obs.	6	9	15
Mean (SD)	417 (14.4)	411 (19.3)	413 (17.2)
Median [Min, Max]	417 [396, 437]	407 [385, 440]	412 [385, 440]
ECG QTcFridericia measurement 2			
Valid Obs.	6	8	14
Mean (SD)	422 (18.9)	414 (16.3)	418 (17.2)
Median [Min, Max]	421 [395, 448]	414 [394, 440]	417 [394, 448]
Missing		1 (11%)	1 (7%)
ECG QTcFridericia measurement 3			
Valid Obs.	6	8	14
Mean (SD)	420 (16.1)	414 (15.4)	416 (15.5)
Median [Min, Max]	418 [395, 438]	411 [396, 442]	417 [395, 442]
Missing		1 (11%)	1 (7%)
ECG QTcFridericia Average			
Valid Obs.	6	8	14
Mean (SD)	420 (16.4)	413 (16.6)	416 (16.2)
Median [Min, Max]	419 [395, 441]	413 [392, 441]	416 [392, 441]
Missing		1 (11%)	1 (7%)
DB Derived ECG QTcF Average Measurement			
Valid Obs.	6	8	14
Mean (SD)	420 (16.4)	413 (16.6)	416 (16.2)
Median [Min, Max]	419 [395, 441]	413 [392, 441]	416 [392, 441]
Missing		1 (11%)	1 (7%)
ECG PR Interval measurement 1			

Variable	Placebo	Active	Total
Valid Obs.	6	9	15
Mean (SD)	151 (20.7)	158 (23.4)	155 (21.8)
Median [Min, Max]	148 [120, 184]	150 [136, 202]	150 [120, 202]
ECG PR Interval measurement 2			
Valid Obs.	6	8	14
Mean (SD)	149 (19.4)	155 (26.0)	152 (22.8)
Median [Min, Max]	147 [120, 180]	146 [130, 204]	146 [120, 204]
Missing		1 (11%)	1 (7%)
ECG PR Interval measurement 3			
Valid Obs.	6	8	14
Mean (SD)	148 (21.6)	161 (29.3)	156 (26.2)
Median [Min, Max]	150 [120, 180]	151 [132, 200]	151 [120, 200]
Missing		1 (11%)	1 (7%)
ECG PR Interval average			
Valid Obs.	6	8	14
Mean (SD)	149 (20.0)	158 (25.5)	154 (22.9)
Median [Min, Max]	150 [120, 181]	149 [133, 202]	149 [120, 202]
Missing		1 (11%)	1 (7%)
DB Derived ECG PR Average Measurement			
Valid Obs.	6	8	14
Mean (SD)	149 (20.0)	158 (25.5)	154 (22.9)
Median [Min, Max]	150 [120, 181]	149 [133, 202]	149 [120, 202]
Missing		1 (11%)	1 (7%)
ECG QRS Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	92.3 (14.8)	90.4 (11.3)	91.2 (12.3)
Median [Min, Max]	90.0 [78.0, 120]	86.0 [78.0, 110]	88.0 [78.0, 120]
ECG QRS Interval measurement 2			
Valid Obs.	6	8	14
Mean (SD)	92.3 (14.6)	88.5 (10.7)	90.1 (12.1)
Median [Min, Max]	89.0 [78.0, 120]	85.0 [80.0, 112]	87.0 [78.0, 120]
Missing		1 (11%)	1 (7%)
ECG QRS Interval measurement 3			
Valid Obs.	6	8	14
Mean (SD)	93.2 (14.3)	88.1 (11.0)	90.3 (12.3)
Median [Min, Max]	89.5 [80.0, 120]	84.0 [78.0, 108]	86.5 [78.0, 120]
Missing		1 (11%)	1 (7%)
ECG QRS Interval Average			
Valid Obs.	6	8	14
Mean (SD)	92.7 (14.5)	88.0 (9.44)	90.0 (11.6)
Median [Min, Max]	89.5 [79.0, 120]	84.5 [79.0, 107]	86.5 [79.0, 120]
Missing		1 (11%)	1 (7%)
DB Derived ECG QRS Average Measurement			
Valid Obs.	6	8	14
Mean (SD)	92.7 (14.5)	88.1 (9.57)	90.1 (11.7)
Median [Min, Max]	89.5 [79.0, 120]	84.5 [79.0, 107]	86.5 [79.0, 120]
Missing		1 (11%)	1 (7%)
ECG RR Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	807 (367)	769 (309)	784 (321)
Median [Min, Max]	931 [78.0, 1040]	876 [88.0, 1000]	909 [78.0, 1040]
ECG RR Interval measurement 2			
Valid Obs.	6	8	14
Mean (SD)	778 (357)	823 (311)	804 (319)
Median [Min, Max]	864 [82.0, 1040]	938 [86.0, 1050]	881 [82.0, 1050]
Missing		1 (11%)	1 (7%)
ECG RR Interval measurement 3			
Valid Obs.	6	8	14
Mean (SD)	777 (352)	806 (305)	794 (313)

Variable	Placebo	Active	Total
Median [Min, Max]	870 [82.0, 1040]	913 [91.0, 1050]	892 [82.0, 1050]
Missing		1 (11%)	1 (7%)
ECG RR Interval average			
Valid Obs.	6	8	14
Mean (SD)	787 (358)	813 (306)	802 (316)
Median [Min, Max]	888 [81.0, 1040]	925 [88.0, 1030]	896 [81.0, 1040]
Missing		1 (11%)	1 (7%)
DB Derived ECG RR Average Measurement			
Valid Obs.	6	8	14
Mean (SD)	787 (358)	813 (306)	802 (316)
Median [Min, Max]	888 [81.0, 1040]	925 [88.0, 1040]	896 [81.0, 1040]
Missing		1 (11%)	1 (7%)
Visit = Visit 1			
Observation	6	9	15
Result of ECG			
Normal	4/6 (67%)	7/9 (78%)	11/15 (73%)
Abnormal NOT Clinically Significant	2/6 (33%)	2/9 (22%)	4/15 (27%)
Does participant show LBBB			
Valid Obs.	6	9	15
Mean (SD)	0 (0)	0 (0)	0 (0)
Median [Min, Max]	0 [0, 0]	0 [0, 0]	0 [0, 0]
EGC QT Interval Measure 1			
Valid Obs.	6	9	15
Mean (SD)	395 (28.2)	394 (24.0)	394 (24.8)
Median [Min, Max]	402 [340, 420]	396 [371, 448]	400 [340, 448]
EGC QT Interval Measure 2			
Valid Obs.	0	2	2
Mean (SD)		426 (36.8)	426 (36.8)
Median [Min, Max]		426 [400, 452]	426 [400, 452]
Missing	6 (100%)	7 (78%)	13 (87%)
EGC QT Interval Measure 3			
Valid Obs.	0	2	2
Mean (SD)		433 (18.4)	433 (18.4)
Median [Min, Max]		433 [420, 446]	433 [420, 446]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG QT Average Measurement			
Valid Obs.	6	9	15
Mean (SD)	395 (28.2)	455 (182)	431 (142)
Median [Min, Max]	402 [340, 420]	400 [371, 936]	400 [340, 936]
DB Derived ECG QT Average Measurement			
Valid Obs.	0	2	2
Mean (SD)		428 (29.7)	428 (29.7)
Median [Min, Max]		428 [407, 449]	428 [407, 449]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG QTcFridericia measurement 1			
Valid Obs.	6	9	15
Mean (SD)	412 (20.3)	409 (17.8)	411 (18.2)
Median [Min, Max]	411 [386, 444]	411 [384, 438]	411 [384, 444]
ECG QTcFridericia measurement 2			
Valid Obs.	0	2	2
Mean (SD)		431 (15.6)	431 (15.6)
Median [Min, Max]		431 [420, 442]	431 [420, 442]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG QTcFridericia measurement 3			
Valid Obs.	0	2	2
Mean (SD)		438 (2.83)	438 (2.83)
Median [Min, Max]		438 [436, 440]	438 [436, 440]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG QTcFridericia Average			

Variable	Placebo	Active	Total
Valid Obs.	6	9	15
Mean (SD)	412 (20.3)	410 (18.6)	411 (18.6)
Median [Min, Max]	411 [386, 444]	411 [384, 439]	411 [384, 444]
DB Derived ECG QTCF Average Measurement			
Valid Obs.	0	2	2
Mean (SD)		433 (8.49)	433 (8.49)
Median [Min, Max]		433 [427, 439]	433 [427, 439]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG PR Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	161 (14.8)	155 (33.4)	157 (26.9)
Median [Min, Max]	157 [148, 188]	148 [116, 230]	150 [116, 230]
ECG PR Interval measurement 2			
Valid Obs.	0	2	2
Mean (SD)		183 (60.8)	183 (60.8)
Median [Min, Max]		183 [140, 226]	183 [140, 226]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG PR Interval measurement 3			
Valid Obs.	0	2	2
Mean (SD)		189 (41.0)	189 (41.0)
Median [Min, Max]		189 [160, 218]	189 [160, 218]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG PR Interval average			
Valid Obs.	6	9	15
Mean (SD)	161 (14.8)	155 (31.7)	157 (25.7)
Median [Min, Max]	157 [148, 188]	148 [116, 225]	150 [116, 225]
DB Derived ECG PR Average Measurement			
Valid Obs.	0	2	2
Mean (SD)		186 (55.2)	186 (55.2)
Median [Min, Max]		186 [147, 225]	186 [147, 225]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG QRS Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	86.0 (7.87)	92.1 (7.34)	89.7 (7.91)
Median [Min, Max]	85.0 [78.0, 98.0]	89.0 [85.0, 106]	88.0 [78.0, 106]
ECG QRS Interval measurement 2			
Valid Obs.	0	2	2
Mean (SD)		103 (4.24)	103 (4.24)
Median [Min, Max]		103 [100, 106]	103 [100, 106]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG QRS Interval measurement 3			
Valid Obs.	0	2	2
Mean (SD)		113 (9.90)	113 (9.90)
Median [Min, Max]		113 [106, 120]	113 [106, 120]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG QRS Interval Average			
Valid Obs.	6	9	15
Mean (SD)	86.0 (7.87)	92.9 (8.55)	90.1 (8.72)
Median [Min, Max]	85.0 [78.0, 98.0]	89.0 [85.0, 107]	88.0 [78.0, 107]
DB Derived ECG QRS Average Measurement			
Valid Obs.	0	2	2
Mean (SD)		107 (0.707)	107 (0.707)
Median [Min, Max]		107 [106, 107]	107 [106, 107]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG RR Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	627 (423)	845 (305)	758 (360)
Median [Min, Max]	857 [70.0, 960]	960 [81.0, 1080]	896 [70.0, 1080]
ECG RR Interval measurement 2			

Variable	Placebo	Active	Total
Valid Obs.	0	2	2
Mean (SD)		1100 (34.6)	1100 (34.6)
Median [Min, Max]		1100 [1070, 1120]	1100 [1070, 1120]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG RR Interval measurement 3			
Valid Obs.	0	2	2
Mean (SD)		1040 (50.2)	1040 (50.2)
Median [Min, Max]		1040 [1000, 1070]	1040 [1000, 1070]
Missing	6 (100%)	7 (78%)	13 (87%)
ECG RR Interval average			
Valid Obs.	6	9	15
Mean (SD)	627 (423)	844 (304)	757 (359)
Median [Min, Max]	857 [70.0, 960]	960 [81.0, 1070]	896 [70.0, 1070]
DB Derived ECG RR Average Measurement			
Valid Obs.	0	2	2
Mean (SD)		1070 (2.83)	1070 (2.83)
Median [Min, Max]		1070 [1070, 1070]	1070 [1070, 1070]
Missing	6 (100%)	7 (78%)	13 (87%)
Visit = Visit 2			
Observation	6	9	15
Result of ECG			
Normal	4/6 (67%)	8/9 (89%)	12/15 (80%)
Abnormal NOT Clinically Significant	2/6 (33%)	1/9 (11%)	3/15 (20%)
Does participant show LBBB			
Valid Obs.	6	9	15
Mean (SD)	0 (0)	0 (0)	0 (0)
Median [Min, Max]	0 [0, 0]	0 [0, 0]	0 [0, 0]
ECG QT Interval Measure 1			
Valid Obs.	6	9	15
Mean (SD)	388 (28.7)	395 (29.9)	392 (28.7)
Median [Min, Max]	379 [352, 424]	393 [350, 460]	390 [350, 460]
ECG_QT Interval Measure 2			
Valid Obs.	0	1	1
Mean (SD)		394 (NA)	394 (NA)
Median [Min, Max]		394 [394, 394]	394 [394, 394]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG_QT Interval Measure 3			
Valid Obs.	0	1	1
Mean (SD)		386 (NA)	386 (NA)
Median [Min, Max]		386 [386, 386]	386 [386, 386]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG QT Average Measurement			
Valid Obs.	6	9	15
Mean (SD)	388 (28.7)	395 (30.0)	392 (28.7)
Median [Min, Max]	379 [352, 424]	391 [350, 460]	390 [350, 460]
DB Derived ECG QT Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		391 (NA)	391 (NA)
Median [Min, Max]		391 [391, 391]	391 [391, 391]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG QTcFridericia measurement 1			
Valid Obs.	6	9	15
Mean (SD)	408 (13.9)	409 (16.4)	409 (14.9)
Median [Min, Max]	407 [389, 428]	413 [385, 443]	410 [385, 443]
ECG QTcFridericia measurement 2			
Valid Obs.	0	1	1
Mean (SD)		397 (NA)	397 (NA)
Median [Min, Max]		397 [397, 397]	397 [397, 397]
Missing	6 (100%)	8 (89%)	14 (93%)

Variable	Placebo	Active	Total
ECG QTcFridericia measurement 3			
Valid Obs.	0	1	1
Mean (SD)		396 (NA)	396 (NA)
Median [Min, Max]		396 [396, 396]	396 [396, 396]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG QTcFridericia Average			
Valid Obs.	6	9	15
Mean (SD)	408 (13.9)	409 (16.4)	409 (14.9)
Median [Min, Max]	407 [389, 428]	413 [385, 443]	410 [385, 443]
DB Derived ECG QTcF Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		396 (NA)	396 (NA)
Median [Min, Max]		396 [396, 396]	396 [396, 396]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG PR Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	156 (20.8)	157 (25.7)	156 (23.1)
Median [Min, Max]	150 [136, 194]	154 [124, 204]	150 [124, 204]
ECG PR Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		158 (NA)	158 (NA)
Median [Min, Max]		158 [158, 158]	158 [158, 158]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG PR Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		152 (NA)	152 (NA)
Median [Min, Max]		152 [152, 152]	152 [152, 152]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG PR Interval average			
Valid Obs.	6	9	15
Mean (SD)	156 (20.8)	157 (25.7)	156 (23.1)
Median [Min, Max]	150 [136, 194]	154 [124, 204]	150 [124, 204]
DB Derived ECG PR Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		156 (NA)	156 (NA)
Median [Min, Max]		156 [156, 156]	156 [156, 156]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG QRS Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	88.7 (7.34)	88.8 (8.69)	88.7 (7.90)
Median [Min, Max]	90.0 [78.0, 96.0]	86.0 [80.0, 104]	90.0 [78.0, 104]
ECG QRS Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		102 (NA)	102 (NA)
Median [Min, Max]		102 [102, 102]	102 [102, 102]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG QRS Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		101 (NA)	101 (NA)
Median [Min, Max]		101 [101, 101]	101 [101, 101]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG QRS Interval Average			
Valid Obs.	6	9	15
Mean (SD)	88.7 (7.34)	89.0 (9.00)	88.9 (8.10)
Median [Min, Max]	90.0 [78.0, 96.0]	86.0 [80.0, 104]	90.0 [78.0, 104]
DB Derived ECG QRS Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		101 (NA)	101 (NA)
Median [Min, Max]		101 [101, 101]	101 [101, 101]

Variable	Placebo	Active	Total
Missing	6 (100%)	8 (89%)	14 (93%)
ECG RR Interval measurement 1			
Valid Obs.	6	9	15
Mean (SD)	569 (373)	908 (106)	772 (293)
Median [Min, Max]	779 [74.0, 880]	882 [720, 1110]	870 [74.0, 1110]
ECG RR Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		974 (NA)	974 (NA)
Median [Min, Max]		974 [974, 974]	974 [974, 974]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG RR Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		923 (NA)	923 (NA)
Median [Min, Max]		923 [923, 923]	923 [923, 923]
Missing	6 (100%)	8 (89%)	14 (93%)
ECG RR Interval average			
Valid Obs.	6	9	15
Mean (SD)	569 (373)	906 (105)	771 (292)
Median [Min, Max]	779 [74.0, 880]	882 [720, 1110]	870 [74.0, 1110]
DB Derived ECG RR Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		956 (NA)	956 (NA)
Median [Min, Max]		956 [956, 956]	956 [956, 956]
Missing	6 (100%)	8 (89%)	14 (93%)
Visit = Visit 3			
Observation	5	9	14
Result of ECG			
Normal	5/5 (100%)	7/9 (78%)	12/14 (86%)
Abnormal NOT Clinically Significant		2/9 (22%)	2/14 (14%)
Does participant show LBBB			
Valid Obs.	5	9	14
Mean (SD)	0 (0)	0 (0)	0 (0)
Median [Min, Max]	0 [0, 0]	0 [0, 0]	0 [0, 0]
EGC QT Interval Measure 1			
Valid Obs.	5	8	13
Mean (SD)	387 (32.8)	398 (25.8)	394 (27.9)
Median [Min, Max]	388 [340, 430]	395 [363, 444]	391 [340, 444]
Missing		1 (11%)	1 (7%)
EGC QT Interval Measure 2			
Valid Obs.	0	1	1
Mean (SD)		386 (NA)	386 (NA)
Median [Min, Max]		386 [386, 386]	386 [386, 386]
Missing	5 (100%)	8 (89%)	13 (93%)
EGC QT Interval Measure 3			
Valid Obs.	0	1	1
Mean (SD)		388 (NA)	388 (NA)
Median [Min, Max]		388 [388, 388]	388 [388, 388]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QT Average Measurement			
Valid Obs.	5	8	13
Mean (SD)	387 (32.8)	398 (26.0)	394 (27.9)
Median [Min, Max]	388 [340, 430]	393 [363, 444]	388 [340, 444]
Missing		1 (11%)	1 (7%)
DB Derived ECG QT Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		388 (NA)	388 (NA)
Median [Min, Max]		388 [388, 388]	388 [388, 388]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QTcFridericia measurement 1			

Variable	Placebo	Active	Total
Valid Obs.	5	9	14
Mean (SD)	415 (17.6)	418 (14.4)	417 (15.0)
Median [Min, Max]	416 [393, 439]	419 [396, 438]	418 [393, 439]
ECG QTcFridericia measurement 2			
Valid Obs.	0	1	1
Mean (SD)		394 (NA)	394 (NA)
Median [Min, Max]		394 [394, 394]	394 [394, 394]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QTcFridericia measurement 3			
Valid Obs.	0	1	1
Mean (SD)		397 (NA)	397 (NA)
Median [Min, Max]		397 [397, 397]	397 [397, 397]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QTcFridericia Average			
Valid Obs.	5	9	14
Mean (SD)	415 (17.6)	418 (14.4)	417 (15.0)
Median [Min, Max]	416 [393, 439]	419 [396, 438]	418 [393, 439]
DB Derived ECG QTcF Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		396 (NA)	396 (NA)
Median [Min, Max]		396 [396, 396]	396 [396, 396]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG PR Interval measurement 1			
Valid Obs.	5	9	14
Mean (SD)	160 (14.8)	151 (28.6)	154 (24.3)
Median [Min, Max]	154 [150, 186]	145 [110, 198]	153 [110, 198]
ECG PR Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		157 (NA)	157 (NA)
Median [Min, Max]		157 [157, 157]	157 [157, 157]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG PR Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		160 (NA)	160 (NA)
Median [Min, Max]		160 [160, 160]	160 [160, 160]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG PR Interval average			
Valid Obs.	5	9	14
Mean (SD)	160 (14.8)	151 (28.5)	154 (24.3)
Median [Min, Max]	154 [150, 186]	145 [110, 198]	153 [110, 198]
DB Derived ECG PR Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		159 (NA)	159 (NA)
Median [Min, Max]		159 [159, 159]	159 [159, 159]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QRS Interval measurement 1			
Valid Obs.	5	9	14
Mean (SD)	93.6 (15.8)	95.0 (11.7)	94.5 (12.7)
Median [Min, Max]	86.0 [80.0, 120]	96.0 [79.0, 113]	92.0 [79.0, 120]
ECG QRS Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		85.0 (NA)	85.0 (NA)
Median [Min, Max]		85.0 [85.0, 85.0]	85.0 [85.0, 85.0]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QRS Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		95.0 (NA)	95.0 (NA)
Median [Min, Max]		95.0 [95.0, 95.0]	95.0 [95.0, 95.0]
Missing	5 (100%)	8 (89%)	13 (93%)

Variable	Placebo	Active	Total
ECG QRS Interval Average			
Valid Obs.	5	9	14
Mean (SD)	93.6 (15.8)	94.4 (11.7)	94.1 (12.7)
Median [Min, Max]	86.0 [80.0, 120]	92.0 [79.0, 113]	90.0 [79.0, 120]
DB Derived ECG QRS Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		92.0 (NA)	92.0 (NA)
Median [Min, Max]		92.0 [92.0, 92.0]	92.0 [92.0, 92.0]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG RR Interval measurement 1			
Valid Obs.	5	9	14
Mean (SD)	734 (385)	844 (128)	805 (242)
Median [Min, Max]	814 [67.0, 1040]	845 [637, 1030]	844 [67.0, 1040]
ECG RR Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		937 (NA)	937 (NA)
Median [Min, Max]		937 [937, 937]	937 [937, 937]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG RR Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		933 (NA)	933 (NA)
Median [Min, Max]		933 [933, 933]	933 [933, 933]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG RR Interval average			
Valid Obs.	5	9	14
Mean (SD)	734 (385)	843 (126)	804 (241)
Median [Min, Max]	814 [67.0, 1040]	845 [637, 1030]	844 [67.0, 1040]
DB Derived ECG RR Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		942 (NA)	942 (NA)
Median [Min, Max]		942 [942, 942]	942 [942, 942]
Missing	5 (100%)	8 (89%)	13 (93%)
Visit = Follow-up			
Observation			
	5	9	14
Result of ECG			
Normal	4/5 (80%)	7/9 (78%)	11/14 (79%)
Abnormal NOT Clinically Significant	1/5 (20%)	2/9 (22%)	3/14 (21%)
Does participant show LBBB			
Valid Obs.	5	9	14
Mean (SD)	0 (0)	0 (0)	0 (0)
Median [Min, Max]	0 [0, 0]	0 [0, 0]	0 [0, 0]
EGC QT Interval Measure 1			
Valid Obs.	5	9	14
Mean (SD)	380 (36.7)	396 (28.9)	391 (31.5)
Median [Min, Max]	384 [330, 424]	387 [360, 440]	387 [330, 440]
EGC_QT Interval Measure 2			
Valid Obs.	0	1	1
Mean (SD)		390 (NA)	390 (NA)
Median [Min, Max]		390 [390, 390]	390 [390, 390]
Missing	5 (100%)	8 (89%)	13 (93%)
EGC_QT Interval Measure 3			
Valid Obs.	0	1	1
Mean (SD)		390 (NA)	390 (NA)
Median [Min, Max]		390 [390, 390]	390 [390, 390]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QT Average Measurement			
Valid Obs.	5	9	14
Mean (SD)	380 (36.7)	396 (28.9)	391 (31.5)
Median [Min, Max]	384 [330, 424]	387 [360, 440]	387 [330, 440]

Variable	Placebo	Active	Total
DB Derived ECG QT Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		390 (NA)	390 (NA)
Median [Min, Max]		390 [390, 390]	390 [390, 390]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QTcFridericia measurement 1			
Valid Obs.	5	9	14
Mean (SD)	406 (18.6)	407 (21.1)	407 (19.5)
Median [Min, Max]	401 [390, 438]	408 [376, 445]	403 [376, 445]
ECG QTcFridericia measurement 2			
Valid Obs.	0	1	1
Mean (SD)		409 (NA)	409 (NA)
Median [Min, Max]		409 [409, 409]	409 [409, 409]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QTcFridericia measurement 3			
Valid Obs.	0	1	1
Mean (SD)		409 (NA)	409 (NA)
Median [Min, Max]		409 [409, 409]	409 [409, 409]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QTcFridericia Average			
Valid Obs.	5	9	14
Mean (SD)	406 (18.6)	407 (21.1)	407 (19.5)
Median [Min, Max]	401 [390, 438]	408 [376, 445]	403 [376, 445]
DB Derived ECG QTcF Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		407 (NA)	407 (NA)
Median [Min, Max]		407 [407, 407]	407 [407, 407]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG PR Interval measurement 1			
Valid Obs.	5	9	14
Mean (SD)	159 (20.1)	150 (18.8)	153 (19.1)
Median [Min, Max]	158 [138, 192]	143 [133, 194]	150 [133, 194]
ECG PR Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		140 (NA)	140 (NA)
Median [Min, Max]		140 [140, 140]	140 [140, 140]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG PR Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		145 (NA)	145 (NA)
Median [Min, Max]		145 [145, 145]	145 [145, 145]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG PR Interval average			
Valid Obs.	5	9	14
Mean (SD)	159 (20.1)	149 (18.9)	153 (19.2)
Median [Min, Max]	158 [138, 192]	143 [133, 194]	148 [133, 194]
DB Derived ECG PR Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		145 (NA)	145 (NA)
Median [Min, Max]		145 [145, 145]	145 [145, 145]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QRS Interval measurement 1			
Valid Obs.	5	9	14
Mean (SD)	87.6 (6.07)	86.2 (7.53)	86.7 (6.83)
Median [Min, Max]	88.0 [80.0, 96.0]	84.0 [80.0, 99.0]	85.0 [80.0, 99.0]
ECG QRS Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		80.0 (NA)	80.0 (NA)
Median [Min, Max]		80.0 [80.0, 80.0]	80.0 [80.0, 80.0]

Variable	Placebo	Active	Total
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QRS Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		84.0 (NA)	84.0 (NA)
Median [Min, Max]		84.0 [84.0, 84.0]	84.0 [84.0, 84.0]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG QRS Interval Average			
Valid Obs.	5	9	14
Mean (SD)	87.6 (6.07)	86.3 (7.43)	86.8 (6.76)
Median [Min, Max]	88.0 [80.0, 96.0]	84.0 [80.0, 99.0]	85.0 [80.0, 99.0]
DB Derived ECG QRS Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		81.0 (NA)	81.0 (NA)
Median [Min, Max]		81.0 [81.0, 81.0]	81.0 [81.0, 81.0]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG RR Interval measurement 1			
Valid Obs.	5	9	14
Mean (SD)	714 (381)	921 (151)	847 (263)
Median [Min, Max]	840 [64.0, 1040]	857 [766, 1260]	854 [64.0, 1260]
ECG RR Interval measurement 2			
Valid Obs.	0	1	1
Mean (SD)		840 (NA)	840 (NA)
Median [Min, Max]		840 [840, 840]	840 [840, 840]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG RR Interval measurement 3			
Valid Obs.	0	1	1
Mean (SD)		880 (NA)	880 (NA)
Median [Min, Max]		880 [880, 880]	880 [880, 880]
Missing	5 (100%)	8 (89%)	13 (93%)
ECG RR Interval average			
Valid Obs.	5	9	14
Mean (SD)	714 (381)	921 (151)	847 (263)
Median [Min, Max]	840 [64.0, 1040]	857 [766, 1260]	857 [64.0, 1260]
DB Derived ECG RR Average Measurement			
Valid Obs.	0	1	1
Mean (SD)		857 (NA)	857 (NA)
Median [Min, Max]		857 [857, 857]	857 [857, 857]
Missing	5 (100%)	8 (89%)	13 (93%)

Table 10 Vital signs Population: Full (n = 15)			
Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
Body temperature			
Valid Obs.	6	9	15
Mean (SD)	37.0 (0.383)	36.7 (0.375)	36.8 (0.397)
Median [Min, Max]	37.1 [36.4, 37.3]	36.6 [36.2, 37.3]	36.8 [36.2, 37.3]
Heart Rate			
Valid Obs.	6	9	15
Mean (SD)	69.5 (9.69)	66.2 (7.41)	67.5 (8.23)
Median [Min, Max]	72.5 [57.0, 79.0]	67.0 [56.0, 81.0]	68.0 [56.0, 81.0]
Systolic Blood Pressure reading 1			
Valid Obs.	6	9	15
Mean (SD)	121 (9.06)	123 (10.4)	122 (9.66)
Median [Min, Max]	125 [108, 129]	126 [103, 137]	126 [103, 137]
Systolic Blood Pressure reading 2			
Valid Obs.	6	9	15
Mean (SD)	123 (7.54)	121 (7.60)	122 (7.38)
Median [Min, Max]	125 [111, 132]	119 [108, 132]	120 [108, 132]
Systolic Blood Pressure average			
Valid Obs.	6	9	15
Mean (SD)	122 (8.07)	122 (8.80)	122 (8.22)
Median [Min, Max]	125 [111, 129]	122 [106, 133]	123 [106, 133]
Derived average			
Valid Obs.	6	9	15
Mean (SD)	122 (8.07)	122 (8.71)	122 (8.16)
Median [Min, Max]	125 [111, 129]	122 [106, 133]	123 [106, 133]
Diastolic blood pressure reading 1			
Valid Obs.	6	9	15
Mean (SD)	77.7 (10.6)	69.3 (10.3)	72.7 (10.9)
Median [Min, Max]	79.5 [59.0, 88.0]	68.0 [59.0, 95.0]	70.0 [59.0, 95.0]
Diastolic blood pressure reading 2			
Valid Obs.	6	9	15
Mean (SD)	77.0 (10.6)	71.1 (9.21)	73.5 (9.87)
Median [Min, Max]	76.5 [63.0, 94.0]	72.0 [52.0, 87.0]	74.0 [52.0, 94.0]
Diastolic blood pressure average			
Valid Obs.	6	9	15
Mean (SD)	77.5 (10.3)	70.4 (9.25)	73.3 (9.96)
Median [Min, Max]	79.5 [61.0, 91.0]	70.0 [56.0, 91.0]	72.0 [56.0, 91.0]
Derived average			
Valid Obs.	6	9	15
Mean (SD)	77.5 (10.3)	70.4 (9.25)	73.3 (9.96)
Median [Min, Max]	79.5 [61.0, 91.0]	70.0 [56.0, 91.0]	72.0 [56.0, 91.0]
Visit = Visit 1			
Observation	6	9	15
Body temperature			
Valid Obs.	6	9	15
Mean (SD)	36.7 (0.175)	36.6 (0.350)	36.6 (0.289)
Median [Min, Max]	36.6 [36.5, 37.0]	36.6 [36.0, 37.2]	36.6 [36.0, 37.2]
Heart Rate			
Valid Obs.	6	9	15
Mean (SD)	73.2 (8.66)	69.3 (9.72)	70.9 (9.20)
Median [Min, Max]	73.5 [59.0, 85.0]	69.0 [55.0, 85.0]	70.0 [55.0, 85.0]
Systolic Blood Pressure reading 1			
Valid Obs.	6	9	15
Mean (SD)	118 (10.2)	121 (8.37)	120 (8.99)
Median [Min, Max]	117 [104, 131]	117 [115, 138]	117 [104, 138]
Diastolic blood pressure reading 1			

Variable	Placebo	Active	Total
Valid Obs.	6	9	15
Mean (SD)	72.8 (10.8)	70.7 (9.49)	71.5 (9.69)
Median [Min, Max]	74.5 [55.0, 87.0]	67.0 [56.0, 87.0]	73.0 [55.0, 87.0]
Visit = Visit 2			
Observation	6	9	15
Body temperature			
Valid Obs.	0	0	0
Missing	6 (100%)	9 (100%)	15 (100%)
Heart Rate			
Valid Obs.	6	9	15
Mean (SD)	72.0 (11.1)	66.4 (9.95)	68.7 (10.4)
Median [Min, Max]	73.0 [57.0, 87.0]	66.0 [53.0, 83.0]	67.0 [53.0, 87.0]
Systolic Blood Pressure reading 1			
Valid Obs.	6	9	15
Mean (SD)	112 (17.7)	124 (11.6)	119 (14.9)
Median [Min, Max]	116 [83.0, 132]	126 [108, 137]	124 [83.0, 137]
Diastolic blood pressure reading 1			
Valid Obs.	6	9	15
Mean (SD)	74.8 (11.1)	72.1 (7.77)	73.2 (8.98)
Median [Min, Max]	74.0 [61.0, 93.0]	70.0 [62.0, 84.0]	70.0 [61.0, 93.0]
Visit = Visit 3			
Observation	5	9	14
Body temperature			
Valid Obs.	0	0	0
Missing	5 (100%)	9 (100%)	14 (100%)
Heart Rate			
Valid Obs.	5	9	14
Mean (SD)	74.6 (7.50)	80.3 (13.2)	78.3 (11.5)
Median [Min, Max]	73.0 [65.0, 84.0]	82.0 [58.0, 99.0]	77.5 [58.0, 99.0]
Systolic Blood Pressure reading 1			
Valid Obs.	5	9	14
Mean (SD)	109 (13.1)	115 (10.4)	113 (11.4)
Median [Min, Max]	113 [89.0, 121]	114 [100, 130]	114 [89.0, 130]
Diastolic blood pressure reading 1			
Valid Obs.	5	9	14
Mean (SD)	72.0 (15.0)	67.7 (11.0)	69.2 (12.2)
Median [Min, Max]	72.0 [53.0, 92.0]	68.0 [46.0, 81.0]	70.0 [46.0, 92.0]
Visit = Follow-up			
Observation	5	9	14
Body temperature			
Valid Obs.	0	0	0
Missing	5 (100%)	9 (100%)	14 (100%)
Heart Rate			
Valid Obs.	5	9	14
Mean (SD)	74.2 (12.6)	67.7 (9.45)	70.0 (10.7)
Median [Min, Max]	66.0 [65.0, 92.0]	69.0 [47.0, 77.0]	68.5 [47.0, 92.0]
Systolic Blood Pressure reading 1			
Valid Obs.	5	9	14
Mean (SD)	110 (12.2)	120 (7.93)	117 (10.6)
Median [Min, Max]	111 [93.0, 124]	117 [107, 129]	117 [93.0, 129]
Diastolic blood pressure reading 1			
Valid Obs.	5	9	14
Mean (SD)	72.2 (12.5)	75.2 (10.4)	74.1 (10.8)
Median [Min, Max]	69.0 [57.0, 89.0]	73.0 [60.0, 90.0]	73.0 [57.0, 90.0]

Table 11 Urinalysis
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
Results of urinalysis			
Normal	4/6 (67%)	4/9 (44%)	8/15 (53%)
Abnormal NOT Clinically Significant	1/6 (17%)	5/9 (56%)	6/15 (40%)
Abnormal Clinically Significant, please describe	1/6 (17%)		1/15 (7%)
Abnormal Clinically Significant, please describe			
Bilirubin level moderate.	1/1 (100%)		1/1 (100%)
Leukocytes			
Negative	6/6 (100%)	7/9 (78%)	13/15 (87%)
Trace		1/9 (11%)	1/15 (7%)
Moderate		1/9 (11%)	1/15 (7%)
Nitrite			
Negative	6/6 (100%)	8/9 (89%)	14/15 (93%)
Positive		1/9 (11%)	1/15 (7%)
Urobilinogen			
0.2mg/dL	6/6 (100%)	9/9 (100%)	15/15 (100%)
Protein			
Negative	6/6 (100%)	6/9 (67%)	12/15 (80%)
Trace		2/9 (22%)	2/15 (13%)
30 mg/dL		1/9 (11%)	1/15 (7%)
pH			
5.0	1/6 (17%)	3/9 (33%)	4/15 (27%)
6.0	3/6 (50%)	3/9 (33%)	6/15 (40%)
6.5	1/6 (17%)	3/9 (33%)	4/15 (27%)
7.0	1/6 (17%)		1/15 (7%)
Blood			
Negative	6/6 (100%)	8/9 (89%)	14/15 (93%)
Large +++		1/9 (11%)	1/15 (7%)
Specific_gravity			
1.000	1/6 (17%)	1/9 (11%)	2/15 (13%)
1.005		2/9 (22%)	2/15 (13%)
1.010	1/6 (17%)	2/9 (22%)	3/15 (20%)
1.015	2/6 (33%)		2/15 (13%)
1.020		1/9 (11%)	1/15 (7%)
1.025	1/6 (17%)	1/9 (11%)	2/15 (13%)
1.030	1/6 (17%)	2/9 (22%)	3/15 (20%)
Ketone			
Negative	6/6 (100%)	7/9 (78%)	13/15 (87%)
Trace 5mg/dL		1/9 (11%)	1/15 (7%)
Small 15mg/dL		1/9 (11%)	1/15 (7%)
Bilirubin			
Negative	5/6 (83%)	8/9 (89%)	13/15 (87%)
Small		1/9 (11%)	1/15 (7%)
Moderate	1/6 (17%)		1/15 (7%)
Glucose			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Visit = Visit 1			
Observation	6	9	15

Variable	Placebo	Active	Total
Results of urinalysis			
Normal	6/6 (100%)	6/9 (67%)	12/15 (80%)
Abnormal NOT Clinically Significant		2/9 (22%)	2/15 (13%)
Abnormal Clinically Significant, please describe		1/9 (11%)	1/15 (7%)
Abnormal Clinically Significant, please describe abnormal as contained small traces of blood and leukocytes.		1/1 (100%)	1/1 (100%)
Leukocytes			
Negative	6/6 (100%)	7/9 (78%)	13/15 (87%)
Trace		1/9 (11%)	1/15 (7%)
Moderate		1/9 (11%)	1/15 (7%)
Nitrite			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Urobilinogen			
0.2mg/dL	6/6 (100%)	9/9 (100%)	15/15 (100%)
Protein			
Negative	5/6 (83%)	9/9 (100%)	14/15 (93%)
Trace	1/6 (17%)		1/15 (7%)
pH			
5.0	2/6 (33%)	1/9 (11%)	3/15 (20%)
6.0	1/6 (17%)	5/9 (56%)	6/15 (40%)
6.5		2/9 (22%)	2/15 (13%)
7.0	2/6 (33%)	1/9 (11%)	3/15 (20%)
7.5	1/6 (17%)		1/15 (7%)
Blood			
Negative	6/6 (100%)	7/9 (78%)	13/15 (87%)
Haemolysed Trace		1/9 (11%)	1/15 (7%)
Small +		1/9 (11%)	1/15 (7%)
Specific_gravity			
1.000	1/6 (17%)		1/15 (7%)
1.010	2/6 (33%)	4/9 (44%)	6/15 (40%)
1.015	3/6 (50%)	3/9 (33%)	6/15 (40%)
1.020		1/9 (11%)	1/15 (7%)
1.025		1/9 (11%)	1/15 (7%)
Ketone			
Negative	5/6 (83%)	9/9 (100%)	14/15 (93%)
Moderate 40mg/dL	1/6 (17%)		1/15 (7%)
Bilirubin			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Glucose			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Visit = Visit 2			
Observation	6	9	15
Results of urinalysis			
Normal	5/6 (83%)	4/9 (44%)	9/15 (60%)
Abnormal NOT Clinically Significant	1/6 (17%)	4/9 (44%)	5/15 (33%)
Abnormal Clinically Significant, please describe		1/9 (11%)	1/15 (7%)
Abnormal Clinically Significant, please describe repeat done likely not clean catch sample		1/1 (100%)	1/1 (100%)

Variable	Placebo	Active	Total
Leukocytes			
Negative	6/6 (100%)	5/9 (56%)	11/15 (73%)
Trace		1/9 (11%)	1/15 (7%)
Small		1/9 (11%)	1/15 (7%)
Moderate		2/9 (22%)	2/15 (13%)
Nitrite			
Negative	6/6 (100%)	8/9 (89%)	14/15 (93%)
Positive		1/9 (11%)	1/15 (7%)
Urobilinogen			
0.2mg/dL	6/6 (100%)	9/9 (100%)	15/15 (100%)
Protein			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
pH			
5.0	1/6 (17%)	2/9 (22%)	3/15 (20%)
6.0	2/6 (33%)	3/9 (33%)	5/15 (33%)
6.5	2/6 (33%)	2/9 (22%)	4/15 (27%)
7.0		1/9 (11%)	1/15 (7%)
7.5	1/6 (17%)		1/15 (7%)
8.0		1/9 (11%)	1/15 (7%)
Blood			
Negative	5/6 (83%)	8/9 (89%)	13/15 (87%)
Non-haemolysed trace	1/6 (17%)		1/15 (7%)
Moderate ++		1/9 (11%)	1/15 (7%)
Specific_gravity			
1.000	1/6 (17%)		1/15 (7%)
1.005	1/6 (17%)	3/9 (33%)	4/15 (27%)
1.010		2/9 (22%)	2/15 (13%)
1.015	1/6 (17%)	1/9 (11%)	2/15 (13%)
1.020	3/6 (50%)	1/9 (11%)	4/15 (27%)
1.025		1/9 (11%)	1/15 (7%)
1.030		1/9 (11%)	1/15 (7%)
Ketone			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Bilirubin			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Glucose			
Negative	6/6 (100%)	9/9 (100%)	15/15 (100%)
Visit = Visit 3			
Observation	5	9	14
Results of urinalysis			
Normal	4/5 (80%)	5/9 (56%)	9/14 (64%)
Abnormal NOT Clinically Significant		3/9 (33%)	3/14 (21%)
Abnormal Clinically Significant, please describe	1/5 (20%)	1/9 (11%)	2/14 (14%)
Abnormal Clinically Significant, please describe			
Traces of protein and specific gravity and pH	1/1 (100%)		1/1 (100%)
Leukocytes			
Negative	5/5 (100%)	6/9 (67%)	11/14 (79%)
Trace		1/9 (11%)	1/14 (7%)
Small		1/9 (11%)	1/14 (7%)
Moderate		1/9 (11%)	1/14 (7%)

Variable	Placebo	Active	Total
Nitrite			
Negative	5/5 (100%)	8/9 (89%)	13/14 (93%)
Positive		1/9 (11%)	1/14 (7%)
Urobilinogen			
0.2mg/dL	5/5 (100%)	9/9 (100%)	14/14 (100%)
Protein			
Negative	4/5 (80%)	7/9 (78%)	11/14 (79%)
Trace	1/5 (20%)	2/9 (22%)	3/14 (21%)
pH			
5.0		2/9 (22%)	2/14 (14%)
6.0	2/5 (40%)	2/9 (22%)	4/14 (29%)
6.5		2/9 (22%)	2/14 (14%)
7.0	1/5 (20%)	3/9 (33%)	4/14 (29%)
7.5	1/5 (20%)		1/14 (7%)
8.5	1/5 (20%)		1/14 (7%)
Blood			
Negative	5/5 (100%)	5/9 (56%)	10/14 (71%)
Haemolysed Trace		1/9 (11%)	1/14 (7%)
Large +++		3/9 (33%)	3/14 (21%)
Specific_gravity			
1.005	1/5 (20%)	2/9 (22%)	3/14 (21%)
1.010	2/5 (40%)	2/9 (22%)	4/14 (29%)
1.015	2/5 (40%)	4/9 (44%)	6/14 (43%)
1.030		1/9 (11%)	1/14 (7%)
Ketone			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Bilirubin			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Glucose			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Visit = Follow-up			
Observation	5	9	14
Results of urinalysis			
Normal	5/5 (100%)	5/9 (56%)	10/14 (71%)
Abnormal NOT Clinically Significant		4/9 (44%)	4/14 (29%)
Abnormal Clinically Significant, please describe			
Missing	5 (100%)	9 (100%)	14 (100%)
Leukocytes			
Negative	4/5 (80%)	5/9 (56%)	9/14 (64%)
Trace		3/9 (33%)	3/14 (21%)
Small	1/5 (20%)		1/14 (7%)
Moderate		1/9 (11%)	1/14 (7%)
Nitrite			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Urobilinogen			
0.2mg/dL	5/5 (100%)	9/9 (100%)	14/14 (100%)
Protein			
Negative	4/5 (80%)	8/9 (89%)	12/14 (86%)
Trace	1/5 (20%)	1/9 (11%)	2/14 (14%)
pH			

Variable	Placebo	Active	Total
5.0	1/5 (20%)		1/14 (7%)
6.0		6/9 (67%)	6/14 (43%)
6.5	3/5 (60%)	2/9 (22%)	5/14 (36%)
7.0	1/5 (20%)		1/14 (7%)
8.0		1/9 (11%)	1/14 (7%)
Blood			
Negative	5/5 (100%)	8/9 (89%)	13/14 (93%)
Non-haemolysed trace		1/9 (11%)	1/14 (7%)
Specific_gravity			
1.005		2/9 (22%)	2/14 (14%)
1.010	2/5 (40%)	3/9 (33%)	5/14 (36%)
1.015	1/5 (20%)	1/9 (11%)	2/14 (14%)
1.020	1/5 (20%)	1/9 (11%)	2/14 (14%)
1.025	1/5 (20%)		1/14 (7%)
1.030		2/9 (22%)	2/14 (14%)
Ketone			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Bilirubin			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Glucose			
Negative	5/5 (100%)	9/9 (100%)	14/14 (100%)
Visit = Unscheduled			
Observation	1	3	4
Results of urinalysis			
Normal		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Abnormal Clinically Significant, please describe			
Missing	1 (100%)	3 (100%)	4 (100%)
Leukocytes			
Negative		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Nitrite			
Negative		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Urobilinogen			
0.2mg/dL		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Protein			
Negative		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
pH			
5.0		1/2 (50%)	1/2 (50%)
6.0		1/2 (50%)	1/2 (50%)
Missing	1 (100%)	1 (33%)	2 (50%)
Blood			
Negative		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Specific_gravity			

Variable	Placebo	Active	Total
1.005		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Ketone			
Negative		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Bilirubin			
Negative		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)
Glucose			
Negative		2/2 (100%)	2/2 (100%)
Missing	1 (100%)	1 (33%)	2 (50%)

Section: Baseline Psychiatric Assessments

Table 12PHQ-9

Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	5	8	13
1. Little interest or pleasure in doing things			
Several days		1/8 (13%)	1/13 (8%)
More than half the days	1/5 (20%)	2/8 (25%)	3/13 (23%)
Nearly every day	4/5 (80%)	5/8 (63%)	9/13 (69%)
2. Feeling down, depressed or hopeless			
Several days		2/8 (25%)	2/13 (15%)
More than half the days	3/5 (60%)	3/8 (38%)	6/13 (46%)
Nearly every day	2/5 (40%)	3/8 (38%)	5/13 (38%)
3. Trouble falling asleep, staying asleep, or sleeping too much			
Several days		1/8 (13%)	1/13 (8%)
More than half the days	2/5 (40%)	2/8 (25%)	4/13 (31%)
Nearly every day	3/5 (60%)	5/8 (63%)	8/13 (62%)
4. Feeling tired or having little energy			
Several days		1/8 (13%)	1/13 (8%)
More than half the days	2/5 (40%)		2/13 (15%)
Nearly every day	3/5 (60%)	7/8 (88%)	10/13 (77%)
5. Poor appetite or overeating			
More than half the days	2/5 (40%)	2/8 (25%)	4/13 (31%)
Nearly every day	3/5 (60%)	6/8 (75%)	9/13 (69%)
6. Feeling bad about yourself - or that you're a			
Several days	1/5 (20%)	2/8 (25%)	3/13 (23%)
More than half the days	1/5 (20%)	2/8 (25%)	3/13 (23%)
Nearly every day	3/5 (60%)	4/8 (50%)	7/13 (54%)
8. Moving or speaking so slowly that other people could have noticed			
Several days	1/5 (20%)	3/8 (38%)	4/13 (31%)
More than half the days	1/5 (20%)	1/8 (13%)	2/13 (15%)
Nearly every day	3/5 (60%)	4/8 (50%)	7/13 (54%)
8. Moving or speaking so slowly that other			
Not at all	3/5 (60%)	2/8 (25%)	5/13 (38%)
Several days	1/5 (20%)	4/8 (50%)	5/13 (38%)
More than half the days	1/5 (20%)	2/8 (25%)	3/13 (23%)
9. Thoughts that you would be better off dead			
Not at all	3/5 (60%)	2/8 (25%)	5/13 (38%)
Several days	2/5 (40%)	6/8 (75%)	8/13 (62%)
Total score:			
Valid Obs.	5	8	13
Mean (SD)	18.8 (3.96)	18.8 (3.41)	18.8 (3.47)
Median [Min, Max]	19.0 [13.0, 24.0]	19.5 [15.0, 23.0]	19.0 [13.0, 24.0]

Patients 10004, 10006 did not complete the form

Table 13HAM-D
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	1	1	2
1. DEPRESSED MOOD			
Communicates feeling states non-verbally	1/1 (100%)	1/1 (100%)	2/2 (100%)
2. FEELINGS OF GUILT			
Present illness is a punishment; delusions of guilt	1/1 (100%)	1/1 (100%)	2/2 (100%)
3. SUICIDE			
Absent	1/1 (100%)		1/2 (50%)
Feels life is not worth living		1/1 (100%)	1/2 (50%)
4. INSOMNIA EARLY			
Complains of occasional difficulty falling asleep i.e. more than half hour		1/1 (100%)	1/2 (50%)
Complains of nightly difficulty falling asleep	1/1 (100%)		1/2 (50%)
5. INSOMNIA MIDDLE			
No difficulty		1/1 (100%)	1/2 (50%)
Patient complains of being restless and disturbed during the night	1/1 (100%)		1/2 (50%)
6. INSOMNIA LATE			
No difficulty	1/1 (100%)	1/1 (100%)	2/2 (100%)
7. WORK AND INTERESTS			
Loss of interest in activity, hobbies, or work either directly reported by patient or indirect in listlessness, indecision and vacillation		1/1 (100%)	1/2 (50%)
Decrease in actual time spent in activities or decrease in productivity	1/1 (100%)		1/2 (50%)
8. RETARDATION			
Normal speech and thought	1/1 (100%)		1/2 (50%)
Obvious retardation at interview		1/1 (100%)	1/2 (50%)
9. AGITATION			
Fidgetiness	1/1 (100%)		1/2 (50%)
Playing with hands, hair, etc.		1/1 (100%)	1/2 (50%)
10. ANXIETY (PSYCHOLOGICAL)			
Worrying about minor matters	1/1 (100%)		1/2 (50%)
Fears expressed without questioning		1/1 (100%)	1/2 (50%)
11. ANXIETY SOMATIC			
Mild		1/1 (100%)	1/2 (50%)
Moderate	1/1 (100%)		1/2 (50%)
12. SOMATIC SYMPTOMS (GASTROINTESTINAL)			
None	1/1 (100%)	1/1 (100%)	2/2 (100%)
13. SOMATIC SYMPTOMS GENERAL			
Heaviness in limbs, back or head. Backache, headache, muscle aches. Loss of energy and fatiguability	1/1 (100%)	1/1 (100%)	2/2 (100%)
14. GENITAL SYMPTOMS			
Mild		1/1 (100%)	1/2 (50%)
Severe	1/1 (100%)		1/2 (50%)
15. HYPOCHONDRIASIS			

Variable	Placebo	Active	Total
Preoccupation with health	1/1 (100%)	1/1 (100%)	2/2 (100%)
16. LOSS OF WEIGHT			
No weight loss or weight loss NOT caused by present illness	1/1 (100%)	1/1 (100%)	2/2 (100%)
17. INSIGHT			
Acknowledges being depressed and ill OR currently not depressed.	1/1 (100%)	1/1 (100%)	2/2 (100%)
TOTAL SCORE			
Valid Obs.	1	1	2
Mean (SD)	22.0 (NA)	23.0 (NA)	22.5 (0.707)
Median [Min, Max]	22.0 [22.0, 22.0]	23.0 [23.0, 23.0]	22.5 [22.0, 23.0]

Patients 10004, 10006 completed HAM-D questionnaire instead of PHQ9

Table 14 MINI clinical interview
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
Participant Primary Diagnosis			
MDD - Current (2 weeks)		1/1 (100%)	1/1 (100%)
Missing	6 (100%)	8 (89%)	14 (93%)
MINI_A1A			
Yes	6/6 (100%)	9/9 (100%)	15/15 (100%)
MINI_A1B			
No		2/9 (22%)	2/15 (13%)
Yes	6/6 (100%)	7/9 (78%)	13/15 (87%)
MINI_A2A			
Yes	6/6 (100%)	9/9 (100%)	15/15 (100%)
MINI_A2B			
No		1/9 (11%)	1/15 (7%)
Yes	6/6 (100%)	8/9 (89%)	14/15 (93%)
MINI_A3 Past 2 weeks			
No	3/6 (50%)		3/15 (20%)
Yes	3/6 (50%)	9/9 (100%)	12/15 (80%)
MINI_A3A past episode			
Yes	5/5 (100%)	9/9 (100%)	14/14 (100%)
Missing	1 (17%)		1 (7%)
MINI_A3B past 2 weeks			
No	1/6 (17%)	1/9 (11%)	2/15 (13%)
Yes	5/6 (83%)	8/9 (89%)	13/15 (87%)
MINI_A3B past episode			
No		1/9 (11%)	1/14 (7%)
Yes	5/5 (100%)	8/9 (89%)	13/14 (93%)
Missing	1 (17%)		1 (7%)
MINI_A3C past 2 weeks			
No	5/6 (83%)	4/9 (44%)	9/15 (60%)
Yes	1/6 (17%)	5/9 (56%)	6/15 (40%)
MINI_A3C past episode			
No	3/5 (60%)		3/14 (21%)
Yes	2/5 (40%)	9/9 (100%)	11/14 (79%)
Missing	1 (17%)		1 (7%)
MINI_A3D past 2 weeks			
Yes	6/6 (100%)	9/9 (100%)	15/15 (100%)
MINI_A3DII Past episode			
No	1/5 (20%)	1/9 (11%)	2/14 (14%)
Yes	4/5 (80%)	8/9 (89%)	12/14 (86%)
Missing	1 (17%)		1 (7%)
MINI_A3EI Past 2 weeks			
No	2/6 (33%)	1/9 (11%)	3/15 (20%)
Yes	4/6 (67%)	8/9 (89%)	12/15 (80%)
MINI_A3EII Past episode			
No	1/5 (20%)		1/14 (7%)
Yes	4/5 (80%)	9/9 (100%)	13/14 (93%)
Missing	1 (17%)		1 (7%)
MINI_A3EII_1 Current episode			
No	3/4 (75%)	8/8 (100%)	11/12 (92%)
Yes	1/4 (25%)		1/12 (8%)
Missing	2 (33%)	1 (11%)	3 (20%)
MINI_A3EII_2 Past episode			
No	2/4 (50%)	9/9 (100%)	11/13 (85%)
Yes	2/4 (50%)		2/13 (15%)
Missing	2 (33%)		2 (13%)
MINI_A3F past 2 weeks			

Variable	Placebo	Active	Total
No	2/6 (33%)	1/9 (11%)	3/15 (20%)
Yes	4/6 (67%)	8/9 (89%)	12/15 (80%)
MINI_A3F past episode			
No	1/5 (20%)		1/14 (7%)
Yes	4/5 (80%)	9/9 (100%)	13/14 (93%)
Missing	1 (17%)		1 (7%)
MINI_A3g Past 2 weeks			
No	5/6 (83%)	5/9 (56%)	10/15 (67%)
Yes	1/6 (17%)	4/9 (44%)	5/15 (33%)
MINI_A3G Past episode			
No	1/5 (20%)	1/9 (11%)	2/14 (14%)
Yes	4/5 (80%)	8/9 (89%)	12/14 (86%)
Missing	1 (17%)		1 (7%)
MINI_A4 Past 2 weeks			
Yes	6/6 (100%)	9/9 (100%)	15/15 (100%)
MINI_A4 Past episode			
Yes	5/5 (100%)	9/9 (100%)	14/14 (100%)
Missing	1 (17%)		1 (7%)
MINI_A5			
No	1/6 (17%)	5/9 (56%)	6/15 (40%)
Yes	5/6 (83%)	4/9 (44%)	9/15 (60%)
Does participant have Major Depressive Episode?			
Yes	6/6 (100%)	9/9 (100%)	15/15 (100%)
Type of Major Depressive Episode - Current			
Current	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing	1 (17%)	1 (11%)	2 (13%)
Not Ticked (Current)			
Not Ticked (Current)	1/1 (100%)	1/1 (100%)	2/2 (100%)
Missing	5 (83%)	8 (89%)	13 (87%)
Type of Major Depressive Episode - Past			
Past	3/3 (100%)	6/6 (100%)	9/9 (100%)
Missing	3 (50%)	3 (33%)	6 (40%)
Not Ticked (Past)			
Not Ticked (Past)	3/3 (100%)	3/3 (100%)	6/6 (100%)
Missing	3 (50%)	6 (67%)	9 (60%)
Type of Major Depressive Episode - Recurrent			
Recurrent	5/5 (100%)	4/4 (100%)	9/9 (100%)
Missing	1 (17%)	5 (56%)	6 (40%)
Recurrent - Not Ticked			
Not Ticked (Recurrent)	1/1 (100%)	5/5 (100%)	6/6 (100%)
Missing	5 (83%)	4 (44%)	9 (60%)
A6 How many episodes of depression did you have i			
Valid Obs.	5	6	11
Mean (SD)	9.60 (7.16)	1.50 (0.837)	5.18 (6.23)
Median [Min, Max]	10.0 [1.00, 18.0]	1.00 [1.00, 3.00]	2.00 [1.00, 18.0]
Missing	1 (17%)	3 (33%)	4 (27%)
Manic Episode			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Hypomanic Episode Current			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Hypomanic Episode Past			
No	5/6 (83%)	9/9 (100%)	14/15 (93%)
Not explored	1/6 (17%)		1/15 (7%)
Hypomanic Symptoms Current			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Hypomanic Symptoms Past			
No	4/6 (67%)	9/9 (100%)	13/15 (87%)
Yes	1/6 (17%)		1/15 (7%)
Not explored	1/6 (17%)		1/15 (7%)

Variable	Placebo	Active	Total
Panic Disorder			
No	5/6 (83%)	6/9 (67%)	11/15 (73%)
Yes	1/6 (17%)	3/9 (33%)	4/15 (27%)
Panic Disorder			
Lifetime	1/1 (100%)	2/3 (67%)	3/4 (75%)
Current		1/3 (33%)	1/4 (25%)
Missing	5 (83%)	6 (67%)	11 (73%)
Agoraphobia Current			
No	5/6 (83%)	7/9 (78%)	12/15 (80%)
Yes	1/6 (17%)	2/9 (22%)	3/15 (20%)
Social Anxiety Disorder (Social Phobia Current)			
No	6/6 (100%)	4/9 (44%)	10/15 (67%)
Yes		5/9 (56%)	5/15 (33%)
O.C.D Current			
No	6/6 (100%)	7/9 (78%)	13/15 (87%)
Yes		2/9 (22%)	2/15 (13%)
Post traumatic Stress Disorder Current			
No	6/6 (100%)	7/9 (78%)	13/15 (87%)
Yes		2/9 (22%)	2/15 (13%)
Alcohol Use Disorder Past 12 Months			
No	5/6 (83%)	9/9 (100%)	14/15 (93%)
Yes	1/6 (17%)		1/15 (7%)
Specify alcohol disorder severity			
Mild	1/1 (100%)		1/1 (100%)
Missing	5 (83%)	9 (100%)	14 (93%)
Substance User Disorder			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
substance severity Specify If:			
Missing	6 (100%)	9 (100%)	15 (100%)
Mood Disorder With Psychotic Features Current			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Mood Disorder With Psychotic Features			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Psychotic Disorder Current			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Psychotic Disorder Lifetime			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Anorexia Nervosa			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Bulimia Nervosa			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Binge Eating Disorder			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Generalized Anxiety Disorder			
No	4/6 (67%)	6/9 (67%)	10/15 (67%)
Yes	2/6 (33%)	3/9 (33%)	5/15 (33%)

Table 15 Assessment of suicidality (C-SSRS) - Screening
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	9	15
1a. Wish to be dead-lifetime (excluding past 6 mon			
Yes	5/6 (83%)	9/9 (100%)	14/15 (93%)
No	1/6 (17%)		1/15 (7%)
1b Wish to be dead-past 6 months			
Yes	3/6 (50%)	5/9 (56%)	8/15 (53%)
No	3/6 (50%)	4/9 (44%)	7/15 (47%)
2a Non-Specific Active Suicidal Thoughts-lifetime			
Yes	5/6 (83%)	8/9 (89%)	13/15 (87%)
No	1/6 (17%)	1/9 (11%)	2/15 (13%)
2b Non-Specific Active Suicidal Thoughts			
Yes	1/6 (17%)	3/9 (33%)	4/15 (27%)
No	5/6 (83%)	6/9 (67%)	11/15 (73%)
3a Active Suicidal Ideation with Any Met			
Yes	3/5 (60%)	7/9 (78%)	10/14 (71%)
No	2/5 (40%)	2/9 (22%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
3b. Active Suicidal Ideation with Any Methods (Not			
Yes	1/3 (33%)	3/7 (43%)	4/10 (40%)
No	2/3 (67%)	4/7 (57%)	6/10 (60%)
Missing	3 (50%)	2 (22%)	5 (33%)
4a. Active Suicidal Ideation with Some Intent to A			
Yes	3/5 (60%)	5/9 (56%)	8/14 (57%)
No	2/5 (40%)	4/9 (44%)	6/14 (43%)
Missing	1 (17%)		1 (7%)
4b. Active Suicidal Ideation with Some Intent to A			
Yes		1/7 (14%)	1/10 (10%)
No	3/3 (100%)	6/7 (86%)	9/10 (90%)
Missing	3 (50%)	2 (22%)	5 (33%)
5a. Active Suicidal Ideation with Specific Plan an			
Yes	1/5 (20%)	3/9 (33%)	4/14 (29%)
No	4/5 (80%)	6/9 (67%)	10/14 (71%)
Missing	1 (17%)		1 (7%)
5b. Active Suicidal Ideation with Specific Plan			
Yes	1/4 (25%)		1/11 (9%)
No	3/4 (75%)	7/7 (100%)	10/11 (91%)
Missing	2 (33%)	2 (22%)	4 (27%)
Most Severe Ideation - type- lifetime			
Type 1	1/5 (20%)	1/9 (11%)	2/14 (14%)
Type 2		1/9 (11%)	1/14 (7%)
Type 3	2/5 (40%)	2/9 (22%)	4/14 (29%)
Type 4	1/5 (20%)	2/9 (22%)	3/14 (21%)
Type 5	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
Most Severe Ideation - type-past 6 months			
Type 1	2/4 (50%)	1/5 (20%)	3/9 (33%)
Type 2		1/5 (20%)	1/9 (11%)
Type 3	1/4 (25%)	2/5 (40%)	3/9 (33%)
Type 4		1/5 (20%)	1/9 (11%)
NA	1/4 (25%)		1/9 (11%)
Missing	2 (33%)	4 (44%)	6 (40%)
Intensity of ideation - FREQUENCY lifetime (exclud			
Less than once a week	1/4 (25%)	2/9 (22%)	3/13 (23%)
Once a week		2/9 (22%)	2/13 (15%)
2-5 times a week	2/4 (50%)	1/9 (11%)	3/13 (23%)
Many times each day	1/4 (25%)	4/9 (44%)	5/13 (38%)

Variable	Placebo	Active	Total
Missing	2 (33%)		2 (13%)
Intensity of ideation - FREQUENCY past 6 months			
Less than once a week	2/3 (67%)	4/6 (67%)	6/9 (67%)
Once a week	1/3 (33%)	1/6 (17%)	2/9 (22%)
Many times each day		1/6 (17%)	1/9 (11%)
Missing	3 (50%)	3 (33%)	6 (40%)
Duration life time excluding past 6 months			
Fleeting - few seconds or minutes	2/4 (50%)	2/9 (22%)	4/13 (31%)
Less than 1hr/some of the time		1/9 (11%)	1/13 (8%)
1 - 4 hrs / a lot of time		2/9 (22%)	2/13 (15%)
4 - 8 hrs/ most of day		2/9 (22%)	2/13 (15%)
More than 8 hrs / persistent or continuous	2/4 (50%)	2/9 (22%)	4/13 (31%)
Missing	2 (33%)		2 (13%)
Duration past 6 months			
Fleeting - few seconds or minutes	2/3 (67%)	2/6 (33%)	4/9 (44%)
Less than 1hr/some of the time		1/6 (17%)	1/9 (11%)
1 - 4 hrs / a lot of time		1/6 (17%)	1/9 (11%)
4 - 8 hrs/ most of day		2/6 (33%)	2/9 (22%)
More than 8 hrs / persistent or continuous	1/3 (33%)		1/9 (11%)
Missing	3 (50%)	3 (33%)	6 (40%)
Controllability lifetime			
Easily able to control thoughts	1/4 (25%)	5/9 (56%)	6/13 (46%)
Can control thoughts with little difficulty	2/4 (50%)		2/13 (15%)
Can control thoughts with some difficulty		1/9 (11%)	1/13 (8%)
Unable to control thoughts	1/4 (25%)	2/9 (22%)	3/13 (23%)
Does not attempt to control thoughts		1/9 (11%)	1/13 (8%)
Missing	2 (33%)		2 (13%)
Controllability past 6 months			
Easily able to control thoughts		4/6 (67%)	4/9 (44%)
Can control thoughts with little difficulty	2/3 (67%)	1/6 (17%)	3/9 (33%)
Can control thoughts with some difficulty		1/6 (17%)	1/9 (11%)
Does not attempt to control thoughts	1/3 (33%)		1/9 (11%)
Missing	3 (50%)	3 (33%)	6 (40%)
Deterrent excluding past 6 months			
Deterrents definitely stopped you from attempting suicide	2/4 (50%)	5/9 (56%)	7/13 (54%)
Deterrents probably stopped you		1/9 (11%)	1/13 (8%)
Uncertain that deterrents stopped you		1/9 (11%)	1/13 (8%)
Deterrents definitely did not stop you	2/4 (50%)	2/9 (22%)	4/13 (31%)
Missing	2 (33%)		2 (13%)
Deterrents past 6 months			
Deterrents definitely stopped you from attempting suicide	1/4 (25%)	6/7 (86%)	7/11 (64%)
Deterrents most likely did not stop you	1/4 (25%)		1/11 (9%)
Does not apply	2/4 (50%)	1/7 (14%)	3/11 (27%)
Missing	2 (33%)	2 (22%)	4 (27%)
Intensity of ideation - REASONS FOR IDEATION lifet			
Equally to get attention, revenge or a reaction from others and to end/stop the pain	1/4 (25%)	1/9 (11%)	2/13 (15%)
Mostly to end or stop the pain		1/9 (11%)	1/13 (8%)
Completely to end or stop the pain	3/4 (75%)	7/9 (78%)	10/13 (77%)
Missing	2 (33%)		2 (13%)
Intensity of ideation - REASONS FOR IDEATION past			
Mostly to end or stop the pain		2/8 (25%)	2/12 (17%)
Completely to end or stop the pain	1/4 (25%)	4/8 (50%)	5/12 (42%)
Does not apply	3/4 (75%)	2/8 (25%)	5/12 (42%)
Missing	2 (33%)	1 (11%)	3 (20%)
Actual attempt made excluding past 6 months			
Yes	1/6 (17%)	4/9 (44%)	5/15 (33%)

Variable	Placebo	Active	Total
No	5/6 (83%)	5/9 (56%)	10/15 (67%)
number of actual attempts made			
Valid Obs.	1	4	5
Mean (SD)	1.00 (NA)	1.75 (0.957)	1.60 (0.894)
Median [Min, Max]	1.00 [1.00, 1.00]	1.50 [1.00, 3.00]	1.00 [1.00, 3.00]
Missing	5 (83%)	5 (56%)	10 (67%)
Has subject engaged in non-suicidal self-injurious			
Yes	2/6 (33%)	3/9 (33%)	5/15 (33%)
No	4/6 (67%)	6/9 (67%)	10/15 (67%)
Actual attempt made past 6 months			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Has subject engaged in non-suicidal self-injurious			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
INTERRUPTED ATTEMPT - lifetime (excluding past 6 mo			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Suicidal behaviour - INTERRUPTED ATTEMPT-past 6 m			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Suicidal behaviour - ABORTED ATTEMPT- lifetime (e			
Yes	2/6 (33%)	1/9 (11%)	3/15 (20%)
No	4/6 (67%)	8/9 (89%)	12/15 (80%)
IF YES - ABORTED ATTEMPT: Number of attempts- lif			
Valid Obs.	2	1	3
Mean (SD)	1.00 (0)	1.00 (NA)	1.00 (0)
Median [Min, Max]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]	1.00 [1.00, 1.00]
Missing	4 (67%)	8 (89%)	12 (80%)
Suicidal behaviour - ABORTED ATTEMPT-past 6 month			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Suicidal behaviour - PREPARATORY ACTS / BEHAVIOUR			
Yes	1/6 (17%)	2/9 (22%)	3/15 (20%)
No	5/6 (83%)	7/9 (78%)	12/15 (80%)
Suicidal behaviour - PREPARATORY ACTS / BEHAVIOUR			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Actual lethality/medical damage most recent attempt			
No physical damage or very minor physical damage		1/4 (25%)	1/5 (20%)
Moderate physical damage	1/1 (100%)	1/4 (25%)	2/5 (40%)
Moderately severe physical damage		2/4 (50%)	2/5 (40%)
Missing	5 (83%)	5 (56%)	10 (67%)
If Actual lethality - 0: potential lethality			
Behaviour likely to result in death despite available medical care		1/1 (100%)	1/1 (100%)
Missing	6 (100%)	8 (89%)	14 (93%)
Actual lethality/Medical damage lethal attempt			
No physical damage or very minor physical damage		1/3 (33%)	1/4 (25%)
Moderate physical damage	1/1 (100%)	1/3 (33%)	2/4 (50%)
Moderately severe physical damage		1/3 (33%)	1/4 (25%)
Missing	5 (83%)	6 (67%)	11 (73%)
If Actual lethality - 0: potential lethality			
Behaviour likely to result in death despite available medical care		1/1 (100%)	1/1 (100%)
Missing	6 (100%)	8 (89%)	14 (93%)
Initial first attempt			

Variable	Placebo	Active	Total
No physical damage or very minor physical damage		1/3 (33%)	1/4 (25%)
Moderate physical damage	1/1 (100%)	1/3 (33%)	2/4 (50%)
Moderately severe physical damage		1/3 (33%)	1/4 (25%)
Missing	5 (83%)	6 (67%)	11 (73%)
If Actual lethality - 0: potential lethality			
Behaviour likely to result in death despite available medical care		1/1 (100%)	1/1 (100%)
Missing	6 (100%)	8 (89%)	14 (93%)
participant have suicidal ideation in the past 6m			
Yes	1/6 (17%)	5/9 (56%)	6/15 (40%)
No	5/6 (83%)	4/9 (44%)	9/15 (60%)
Please enter Intensity of ideation score Intensity			
Valid Obs.	1	5	6
Mean (SD)	3.00 (NA)	2.60 (1.14)	2.67 (1.03)
Median [Min, Max]	3.00 [3.00, 3.00]	3.00 [1.00, 4.00]	3.00 [1.00, 4.00]
Missing	5 (83%)	4 (44%)	9 (60%)
If yes, is this clinically significant suicidalit			
No	1/1 (100%)	5/5 (100%)	6/6 (100%)
Missing	5 (83%)	4 (44%)	9 (60%)
Does participant have suicidal ideation >6months a			
Yes	4/6 (67%)	9/9 (100%)	13/15 (87%)
No	2/6 (33%)		2/15 (13%)
if yes, enter Intensity of ideation score Inten			
Valid Obs.	4	9	13
Mean (SD)	3.25 (1.71)	3.56 (1.42)	3.46 (1.45)
Median [Min, Max]	3.50 [1.00, 5.00]	4.00 [1.00, 5.00]	4.00 [1.00, 5.00]
Missing	2 (33%)		2 (13%)
if yes, is this clinically significant suicidality			
No	4/4 (100%)	9/9 (100%)	13/13 (100%)
Missing	2 (33%)		2 (13%)
Does participant have suicidal behaviour in the pa			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Does participant have suicidal behaviour >6months			
Yes	4/6 (67%)	5/9 (56%)	9/15 (60%)
No	2/6 (33%)	4/9 (44%)	6/15 (40%)
If yes,is this clinically significant? MT6M			
No	4/4 (100%)	5/5 (100%)	9/9 (100%)
Missing	2 (33%)	4 (44%)	6 (40%)

Table 16 Assessment of suicidality (C-SSRS) - All other visits
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
Wish to be dead since last visit			
Yes	2/6 (33%)	5/9 (56%)	7/15 (47%)
No	4/6 (67%)	4/9 (44%)	8/15 (53%)
Non-Specific Active Suicidal Thoughts-since last v			
Yes	1/6 (17%)	4/9 (44%)	5/15 (33%)
No	5/6 (83%)	5/9 (56%)	10/15 (67%)
Active Suicidal Ideation with Any Methods (Not Pla			
Yes	1/2 (50%)	4/5 (80%)	5/7 (71%)
No	1/2 (50%)	1/5 (20%)	2/7 (29%)
Missing	4 (67%)	4 (44%)	8 (53%)
Active Suicidal Ideation with Some Intent to Act,			
No	2/2 (100%)	5/5 (100%)	7/7 (100%)
Missing	4 (67%)	4 (44%)	8 (53%)
Active Suicidal Ideation with Specific Plan and In			
No	2/2 (100%)	5/5 (100%)	7/7 (100%)
Missing	4 (67%)	4 (44%)	8 (53%)
Most Severe Ideation -since last visit			
Type 1		3/6 (50%)	3/7 (43%)
Type 3	1/1 (100%)	3/6 (50%)	4/7 (57%)
Missing	5 (83%)	3 (33%)	8 (53%)
Intensity of ideation - FREQUENCY -since last visi			
Less than once a week		2/6 (33%)	2/7 (29%)
2-5 times a week	1/1 (100%)	3/6 (50%)	4/7 (57%)
Many times each day		1/6 (17%)	1/7 (14%)
Missing	5 (83%)	3 (33%)	8 (53%)
Intensity of ideation - DURATION -since last visit			
Fleeting - few seconds or minutes	1/1 (100%)	3/6 (50%)	4/7 (57%)
Less than 1hr/some of the time		3/6 (50%)	3/7 (43%)
Missing	5 (83%)	3 (33%)	8 (53%)
Intensity of ideation - CONTROLLABILITY - since la			
Easily able to control thoughts		3/6 (50%)	3/7 (43%)
Can control thoughts with little difficulty	1/1 (100%)	1/6 (17%)	2/7 (29%)
Can control thoughts with some difficulty		1/6 (17%)	1/7 (14%)
Unable to control thoughts		1/6 (17%)	1/7 (14%)
Missing	5 (83%)	3 (33%)	8 (53%)
Intensity of ideation - DETERRENTS - since last vi			
Deterrents definitely stopped you from attempting suicide		5/6 (83%)	5/7 (71%)
Deterrents definitely did not stop you	1/1 (100%)		1/7 (14%)
Does not apply		1/6 (17%)	1/7 (14%)
Missing	5 (83%)	3 (33%)	8 (53%)
Intensity of ideation - REASONS FOR IDEATION since			
Mostly to end or stop the pain		1/6 (17%)	1/7 (14%)
Completely to end or stop the pain	1/1 (100%)	5/6 (83%)	6/7 (86%)
Missing	5 (83%)	3 (33%)	8 (53%)
Actual attempt since last visit			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Non suicidal self injurious since last visit			
Yes		1/9 (11%)	1/15 (7%)
No	6/6 (100%)	8/9 (89%)	14/15 (93%)
Interrupted attempt since last visit			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Aborted attempt since last visit			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Preparatory acts/ behavior since last visit			

Variable	Placebo	Active	Total
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Suicidal ideation since last visit			
Yes	1/6 (17%)	5/9 (56%)	6/15 (40%)
No	5/6 (83%)	4/9 (44%)	9/15 (60%)
Intensity of ideation score			
Valid Obs.	1	5	6
Mean (SD)	3.00 (NA)	1.80 (1.10)	2.00 (1.10)
Median [Min, Max]	3.00 [3.00, 3.00]	1.00 [1.00, 3.00]	2.00 [1.00, 3.00]
Missing	5 (83%)	4 (44%)	9 (60%)
If yes, is this clinically significant suicidality			
No	1/1 (100%)	5/5 (100%)	6/6 (100%)
Missing	5 (83%)	4 (44%)	9 (60%)
Since Last Visit, does participant have suicidal b			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
If yes, is this clinically significant?			
Missing	6 (100%)	9 (100%)	15 (100%)
Visit = Visit 2			
Observation	6	9	15
Wish to be dead since last visit			
Yes	1/6 (17%)	2/9 (22%)	3/15 (20%)
No	5/6 (83%)	7/9 (78%)	12/15 (80%)
Non-Specific Active Suicidal Thoughts-since last v			
Yes	1/6 (17%)	1/9 (11%)	2/15 (13%)
No	5/6 (83%)	8/9 (89%)	13/15 (87%)
Active Suicidal Ideation with Any Methods (Not Pla			
Yes	1/2 (50%)	1/3 (33%)	2/5 (40%)
No	1/2 (50%)	2/3 (67%)	3/5 (60%)
Missing	4 (67%)	6 (67%)	10 (67%)
Active Suicidal Ideation with Some Intent to Act,			
No	2/2 (100%)	3/3 (100%)	5/5 (100%)
Missing	4 (67%)	6 (67%)	10 (67%)
Active Suicidal Ideation with Specific Plan and In			
No	2/2 (100%)	3/3 (100%)	5/5 (100%)
Missing	4 (67%)	6 (67%)	10 (67%)
Most Severe Ideation -since last visit			
Type 1		2/3 (67%)	2/4 (50%)
Type 3		1/3 (33%)	1/4 (25%)
Type 5	1/1 (100%)		1/4 (25%)
Missing	5 (83%)	6 (67%)	11 (73%)
Intensity of ideation - FREQUENCY -since last visi			
Less than once a week		1/3 (33%)	1/4 (25%)
Once a week		1/3 (33%)	1/4 (25%)
2-5 times a week		1/3 (33%)	1/4 (25%)
Daily or almost daily	1/1 (100%)		1/4 (25%)
Missing	5 (83%)	6 (67%)	11 (73%)
Intensity of ideation - DURATION -since last visit			
Fleeting - few seconds or minutes		2/3 (67%)	2/4 (50%)
1 - 4 hrs / a lot of time	1/1 (100%)	1/3 (33%)	2/4 (50%)
Missing	5 (83%)	6 (67%)	11 (73%)
Intensity of ideation - CONTROLLABILITY - since la			
Easily able to control thoughts		2/3 (67%)	2/4 (50%)
Can control thoughts with little difficulty		1/3 (33%)	1/4 (25%)
Can control thoughts with some difficulty	1/1 (100%)		1/4 (25%)
Missing	5 (83%)	6 (67%)	11 (73%)
Intensity of ideation - DETERRENTS - since last vi			
Deterrments definitely stopped you from attempting suicide		3/3 (100%)	3/4 (75%)
Deterrments definitely did not stop you	1/1 (100%)		1/4 (25%)

Variable	Placebo	Active	Total
Missing	5 (83%)	6 (67%)	11 (73%)
Intensity of ideation - REASONS FOR IDEATION since			
Mostly to end or stop the pain		2/3 (67%)	2/4 (50%)
Completely to end or stop the pain	1/1 (100%)	1/3 (33%)	2/4 (50%)
Missing	5 (83%)	6 (67%)	11 (73%)
Actual attempt since last visit			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Non suicidal self injurious since last visit			
Yes		1/9 (11%)	1/15 (7%)
No	6/6 (100%)	8/9 (89%)	14/15 (93%)
Interrupted attempt since last visit			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Aborted attempt since last visit			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Preparatory acts/ behavior since last visit			
No	6/6 (100%)	9/9 (100%)	15/15 (100%)
Suicidal ideation since last visit			
Yes	1/6 (17%)	3/9 (33%)	4/15 (27%)
No	5/6 (83%)	6/9 (67%)	11/15 (73%)
Intensity of ideation score			
Valid Obs.	1	3	4
Mean (SD)	3.00 (NA)	1.67 (1.15)	2.00 (1.15)
Median [Min, Max]	3.00 [3.00, 3.00]	1.00 [1.00, 3.00]	2.00 [1.00, 3.00]
Missing	5 (83%)	6 (67%)	11 (73%)
If yes, is this clinically significant suicidality			
No	1/1 (100%)	3/3 (100%)	4/4 (100%)
Missing	5 (83%)	6 (67%)	11 (73%)
Since Last Visit, does participant have suicidal b			
Yes	1/6 (17%)		1/15 (7%)
No	5/6 (83%)	9/9 (100%)	14/15 (93%)
If yes, is this clinically significant?			
No	1/1 (100%)		1/1 (100%)
Missing	5 (83%)	9 (100%)	14 (93%)
Visit = Visit 3			
Observation	5	9	14
Wish to be dead since last visit			
Yes	1/5 (20%)	3/9 (33%)	4/14 (29%)
No	4/5 (80%)	6/9 (67%)	10/14 (71%)
Non-Specific Active Suicidal Thoughts-since last v			
Yes	1/5 (20%)	1/9 (11%)	2/14 (14%)
No	4/5 (80%)	8/9 (89%)	12/14 (86%)
Active Suicidal Ideation with Any Methods (Not Pla			
Yes	1/2 (50%)	1/7 (14%)	2/9 (22%)
No	1/2 (50%)	6/7 (86%)	7/9 (78%)
Missing	3 (60%)	2 (22%)	5 (36%)
Active Suicidal Ideation with Some Intent to Act,			
No	2/2 (100%)	4/4 (100%)	6/6 (100%)
Missing	3 (60%)	5 (56%)	8 (57%)
Active Suicidal Ideation with Specific Plan and In			
No	2/2 (100%)	4/4 (100%)	6/6 (100%)
Missing	3 (60%)	5 (56%)	8 (57%)
Most Severe Ideation -since last visit			
Type 1		3/4 (75%)	3/5 (60%)
Type 2		1/4 (25%)	1/5 (20%)
Type 3	1/1 (100%)		1/5 (20%)
Missing	4 (80%)	5 (56%)	9 (64%)
Intensity of ideation - FREQUENCY -since last visi			
Less than once a week		3/4 (75%)	3/5 (60%)

Variable	Placebo	Active	Total
Once a week		1/4 (25%)	1/5 (20%)
2-5 times a week	1/1 (100%)		1/5 (20%)
Missing	4 (80%)	5 (56%)	9 (64%)
Intensity of ideation - DURATION -since last visit			
Fleeting - few seconds or minutes	1/1 (100%)	3/4 (75%)	4/5 (80%)
1 - 4 hrs / a lot of time		1/4 (25%)	1/5 (20%)
Missing	4 (80%)	5 (56%)	9 (64%)
Intensity of ideation - CONTROLLABILITY - since la			
Easily able to control thoughts		2/4 (50%)	2/5 (40%)
Can control thoughts with little difficulty		1/4 (25%)	1/5 (20%)
Can control thoughts with some difficulty	1/1 (100%)		1/5 (20%)
Unable to control thoughts		1/4 (25%)	1/5 (20%)
Missing	4 (80%)	5 (56%)	9 (64%)
Intensity of ideation - DETERRENTS - since last vi			
Deterrents definitely stopped you from attempting suicide		2/4 (50%)	2/5 (40%)
Deterrents probably stopped you		1/4 (25%)	1/5 (20%)
Deterrents definitely did not stop you	1/1 (100%)		1/5 (20%)
Does not apply		1/4 (25%)	1/5 (20%)
Missing	4 (80%)	5 (56%)	9 (64%)
Intensity of ideation - REASONS FOR IDEATION since			
Completely to get attention, revenge or a reaction from others		1/4 (25%)	1/5 (20%)
Mostly to end or stop the pain		1/4 (25%)	1/5 (20%)
Completely to end or stop the pain	1/1 (100%)	1/4 (25%)	2/5 (40%)
Does not apply		1/4 (25%)	1/5 (20%)
Missing	4 (80%)	5 (56%)	9 (64%)
Actual attempt since last visit			
No	5/5 (100%)	9/9 (100%)	14/14 (100%)
Non suicidal self injurious since last visit			
Yes		1/9 (11%)	1/14 (7%)
No	5/5 (100%)	8/9 (89%)	13/14 (93%)
Interrupted attempt since last visit			
No	5/5 (100%)	9/9 (100%)	14/14 (100%)
Aborted attempt since last visit			
No	5/5 (100%)	9/9 (100%)	14/14 (100%)
Preparatory acts/ behavior since last visit			
No	5/5 (100%)	9/9 (100%)	14/14 (100%)
Suicidal ideation since last visit			
Yes	1/5 (20%)	4/9 (44%)	5/14 (36%)
No	4/5 (80%)	5/9 (56%)	9/14 (64%)
Intensity of ideation score			
Valid Obs.	1	4	5
Mean (SD)	3.00 (NA)	2.25 (1.89)	2.40 (1.67)
Median [Min, Max]	3.00 [3.00, 3.00]	1.50 [1.00, 5.00]	2.00 [1.00, 5.00]
Missing	4 (80%)	5 (56%)	9 (64%)
If yes, is this clinically significant suicidality			
Yes		1/4 (25%)	1/5 (20%)
No	1/1 (100%)	3/4 (75%)	4/5 (80%)
Missing	4 (80%)	5 (56%)	9 (64%)
Since Last Visit, does participant have suicidal b			
No	5/5 (100%)	9/9 (100%)	14/14 (100%)
If yes,is this clinically significant?			
Missing	5 (100%)	9 (100%)	14 (100%)
Visit = Follow-up			
Observation	5	9	14
Wish to be dead since last visit			
Yes		1/9 (11%)	1/14 (7%)

Variable	Placebo	Active	Total
No	5/5 (100%)	8/9 (89%)	13/14 (93%)
Non-Specific Active Suicidal Thoughts-since last v			
No	5/5 (100%)	9/9 (100%)	14/14 (100%)
Active Suicidal Ideation with Any Methods (Not Pla			
No	1/1 (100%)	3/3 (100%)	4/4 (100%)
Missing	4 (80%)	6 (67%)	10 (71%)
Active Suicidal Ideation with Some Intent to Act,			
No	1/1 (100%)	2/2 (100%)	3/3 (100%)
Missing	4 (80%)	7 (78%)	11 (79%)
Active Suicidal Ideation with Specific Plan and In			
No	1/1 (100%)	2/2 (100%)	3/3 (100%)
Missing	4 (80%)	7 (78%)	11 (79%)
Most Severe Ideation -since last visit			
Type 1		1/2 (50%)	1/2 (50%)
NA		1/2 (50%)	1/2 (50%)
Missing	5 (100%)	7 (78%)	12 (86%)
Intensity of ideation - FREQUENCY -since last visi			
2-5 times a week		1/1 (100%)	1/1 (100%)
Missing	5 (100%)	8 (89%)	13 (93%)
Intensity of ideation - DURATION -since last visit			
Fleeting - few seconds or minutes		1/1 (100%)	1/1 (100%)
Missing	5 (100%)	8 (89%)	13 (93%)
Intensity of ideation - CONTROLLABILITY - since la			
Can control thoughts with little difficulty		1/1 (100%)	1/1 (100%)
Missing	5 (100%)	8 (89%)	13 (93%)
Intensity of ideation - DETERRENTS - since last vi			
Deterrants definitely stopped you from attempting suicide		1/1 (100%)	1/1 (100%)
Missing	5 (100%)	8 (89%)	13 (93%)
Intensity of ideation - REASONS FOR IDEATION since			
Completely to get attention, revenge or a reaction from others		1/1 (100%)	1/1 (100%)
Missing	5 (100%)	8 (89%)	13 (93%)
Actual attempt since last visit			
No	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing		1 (11%)	1 (7%)
Non suicidal self injurious since last visit			
No	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing		1 (11%)	1 (7%)
Interrupted attempt since last visit			
No	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing		1 (11%)	1 (7%)
Aborted attempt since last visit			
No	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing		1 (11%)	1 (7%)
Preparatory acts/ behavior since last visit			
No	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing		1 (11%)	1 (7%)
Suicidal ideation since last visit			
Yes		1/9 (11%)	1/14 (7%)
No	5/5 (100%)	8/9 (89%)	13/14 (93%)
Intensity of ideation score			
Valid Obs.	0	1	1
Mean (SD)		1.00 (NA)	1.00 (NA)
Median [Min, Max]		1.00 [1.00, 1.00]	1.00 [1.00, 1.00]
Missing	5 (100%)	8 (89%)	13 (93%)
If yes, is this clinically significant suicidality			
No		1/1 (100%)	1/1 (100%)

Variable	Placebo	Active	Total
Missing	5 (100%)	8 (89%)	13 (93%)
Since Last Visit, does participant have suicidal b			
No	5/5 (100%)	9/9 (100%)	14/14 (100%)
If yes,is this clinically significant?			
Missing	5 (100%)	9 (100%)	14 (100%)

Table 17 Childhood Trauma Questionnaire
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
I didnt have enough to eat			
Never true	4/6 (67%)	3/9 (33%)	7/15 (47%)
Rarely true	1/6 (17%)	5/9 (56%)	6/15 (40%)
Sometimes true		1/9 (11%)	1/15 (7%)
Often true	1/6 (17%)		1/15 (7%)
I knew that there was someone to take care of me a			
Never true		1/9 (11%)	1/15 (7%)
Rarely true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Sometimes true	2/6 (33%)	1/9 (11%)	3/15 (20%)
Often true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Very often true	2/6 (33%)	5/9 (56%)	7/15 (47%)
People in my family called me things like stupid o			
Never true	3/6 (50%)	3/9 (33%)	6/15 (40%)
Rarely true		3/9 (33%)	3/15 (20%)
Sometimes true	3/6 (50%)	2/9 (22%)	5/15 (33%)
Often true		1/9 (11%)	1/15 (7%)
My parents were too drunk or high to take care of			
Never true	2/6 (33%)	8/9 (89%)	10/15 (67%)
Rarely true	3/6 (50%)		3/15 (20%)
Sometimes true	1/6 (17%)		1/15 (7%)
Often true		1/9 (11%)	1/15 (7%)
There was someone in my family who helped me feel			
Rarely true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Sometimes true	2/6 (33%)	1/9 (11%)	3/15 (20%)
Often true	2/6 (33%)	2/9 (22%)	4/15 (27%)
Very often true	1/6 (17%)	5/9 (56%)	6/15 (40%)
I had to wear dirty clothes			
Never true	2/6 (33%)	6/9 (67%)	8/15 (53%)
Rarely true	1/6 (17%)	2/9 (22%)	3/15 (20%)
Sometimes true	2/6 (33%)	1/9 (11%)	3/15 (20%)
Often true	1/6 (17%)		1/15 (7%)
I felt loved			
Never true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Rarely true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Sometimes true	2/6 (33%)	2/9 (22%)	4/15 (27%)
Often true		3/9 (33%)	3/15 (20%)
Very often true	2/6 (33%)	2/9 (22%)	4/15 (27%)
I thought that my parents wished I had never been			
Never true	3/6 (50%)	7/9 (78%)	10/15 (67%)
Sometimes true		1/9 (11%)	1/15 (7%)
Often true	3/6 (50%)	1/9 (11%)	4/15 (27%)
I got hit by someone in my family that I had to se			
Never true	4/6 (67%)	8/9 (89%)	12/15 (80%)
Rarely true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Sometimes true	1/6 (17%)		1/15 (7%)
There was nothing I wanted to change about my fami			
Never true	1/6 (17%)	2/9 (22%)	3/15 (20%)
Rarely true	2/6 (33%)	1/9 (11%)	3/15 (20%)
Sometimes true		4/9 (44%)	4/15 (27%)
Often true	2/6 (33%)	1/9 (11%)	3/15 (20%)
Very often true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Minimization/Denial score			
0	5/6 (83%)	8/9 (89%)	13/15 (87%)
1	1/6 (17%)	1/9 (11%)	2/15 (13%)
People in my family hit me so hard that it left me			

Variable	Placebo	Active	Total
Never true	4/6 (67%)	7/9 (78%)	11/15 (73%)
Rarely true	1/6 (17%)		1/15 (7%)
Sometimes true	1/6 (17%)		1/15 (7%)
Often true		1/9 (11%)	1/15 (7%)
Very often true		1/9 (11%)	1/15 (7%)
I was punished with a belt, a board, a cord, or so			
Never true	3/6 (50%)	8/9 (89%)	11/15 (73%)
Rarely true	2/6 (33%)		2/15 (13%)
Sometimes true	1/6 (17%)		1/15 (7%)
Very often true		1/9 (11%)	1/15 (7%)
People in my family looked out for each other			
Never true	1/5 (20%)		1/14 (7%)
Rarely true	1/5 (20%)	1/9 (11%)	2/14 (14%)
Sometimes true	2/5 (40%)	5/9 (56%)	7/14 (50%)
Often true	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
People in my family said hurtful or insulting thin			
Never true	2/6 (33%)	4/9 (44%)	6/15 (40%)
Sometimes true	2/6 (33%)	3/9 (33%)	5/15 (33%)
Often true	2/6 (33%)	2/9 (22%)	4/15 (27%)
I believe I was physically abused			
Never true	4/6 (67%)	7/9 (78%)	11/15 (73%)
Sometimes true	2/6 (33%)		2/15 (13%)
Often true		1/9 (11%)	1/15 (7%)
Very often true		1/9 (11%)	1/15 (7%)
I had the perfect childhood.			
Never true	4/6 (67%)	5/9 (56%)	9/15 (60%)
Rarely true	1/6 (17%)	2/9 (22%)	3/15 (20%)
Sometimes true		1/9 (11%)	1/15 (7%)
Often true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Minimization/Denial score			
0	6/6 (100%)	9/9 (100%)	15/15 (100%)
I got hit so hard or beaten so badly that it was n			
Never true	4/6 (67%)	8/9 (89%)	12/15 (80%)
Rarely true	2/6 (33%)	1/9 (11%)	3/15 (20%)
I felt that someone in my family hated me			
Never true	3/6 (50%)	3/9 (33%)	6/15 (40%)
Sometimes true	3/6 (50%)		3/15 (20%)
Often true		3/9 (33%)	3/15 (20%)
Very often true		3/9 (33%)	3/15 (20%)
People in my family felt close to each other			
Never true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Rarely true	1/6 (17%)	2/9 (22%)	3/15 (20%)
Sometimes true	3/6 (50%)	4/9 (44%)	7/15 (47%)
Often true		1/9 (11%)	1/15 (7%)
Very often true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Someone tried to touch me in a sexual way, or trie			
Never true	4/6 (67%)	5/9 (56%)	9/15 (60%)
Rarely true	2/6 (33%)		2/15 (13%)
Sometimes true		1/9 (11%)	1/15 (7%)
Often true		1/9 (11%)	1/15 (7%)
Very often true		2/9 (22%)	2/15 (13%)
Someone threatened to hurt me or tell lies about m			
Never true	5/6 (83%)	6/9 (67%)	11/15 (73%)
Rarely true	1/6 (17%)		1/15 (7%)
Sometimes true		1/9 (11%)	1/15 (7%)
Very often true		2/9 (22%)	2/15 (13%)
I had the best family in the World			
Never true	2/6 (33%)	4/9 (44%)	6/15 (40%)

Variable	Placebo	Active	Total
Rarely true	2/6 (33%)	3/9 (33%)	5/15 (33%)
Sometimes true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Often true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Minimization/Denial score			
0	6/6 (100%)	9/9 (100%)	15/15 (100%)
Someone tried to make me do sexual things or watch			
Never true	5/6 (83%)	6/9 (67%)	11/15 (73%)
Sometimes true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Very often true		2/9 (22%)	2/15 (13%)
Someone molested me.			
Never true	5/6 (83%)	6/9 (67%)	11/15 (73%)
Rarely true	1/6 (17%)		1/15 (7%)
Sometimes true		1/9 (11%)	1/15 (7%)
Very often true		2/9 (22%)	2/15 (13%)
I believe that I was emotionally abused			
Never true	3/6 (50%)	3/9 (33%)	6/15 (40%)
Rarely true	1/6 (17%)	2/9 (22%)	3/15 (20%)
Sometimes true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Often true	1/6 (17%)	2/9 (22%)	3/15 (20%)
Very often true		1/9 (11%)	1/15 (7%)
There was someone to take me to the doctor if I ne			
Never true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Sometimes true	1/6 (17%)		1/15 (7%)
Often true	2/6 (33%)	3/9 (33%)	5/15 (33%)
Very often true	2/6 (33%)	5/9 (56%)	7/15 (47%)
I believe that I was sexually abused			
Never true	4/6 (67%)	7/9 (78%)	11/15 (73%)
Rarely true	1/6 (17%)		1/15 (7%)
Sometimes true	1/6 (17%)	1/9 (11%)	2/15 (13%)
Very often true		1/9 (11%)	1/15 (7%)
My family was a source of strength and support.			
Never true	2/6 (33%)	1/9 (11%)	3/15 (20%)
Rarely true		2/9 (22%)	2/15 (13%)
Sometimes true	2/6 (33%)	5/9 (56%)	7/15 (47%)
Often true	1/6 (17%)		1/15 (7%)
Very often true	1/6 (17%)	1/9 (11%)	2/15 (13%)

Section: Medical History
Table 18 Family history of depression
Listing Population: Full (n = 15)

Participant ID	Group	Site	Family history of depression	Total number of relatives with depression	Relatives	Number of relatives
10019	Placebo	N01	Yes	2	Parent	2
10036	Active	N01	No			
10038	Placebo	N01	Yes	2	Parent	2
30002	Active	N03	Yes	2	Uncles	1
					Grandparents	1
30006	Placebo	N03	Yes	7	Parent	1
					Grandparents	3
					Half-siblings	3
30011	Placebo	N03	Yes	1	Sibling	1
30013	Active	N03	Yes	2	Sibling	1
					Aunts	1
30015	Active	N03	Yes	2	Parent	1
					Aunts	1
40005	Active	N04	No			
60004	Placebo	N06	Unknown			
60009	Active	N06	No			
60010	Active	N06	Yes	2	Sibling	1
					Grandparents	1
60014	Active	N06	Yes	2	Aunts	2

Patient 10004 did not complete the form

Table 19 Smoking history Population: Full (n = 15)			
Variable	Placebo	Active	Total
Visit = Screening			
Observation	6	8	14
Does the participant smoke tobacco (including e-cigarettes)?			
Current Smoker	1/5 (20%)	1/8 (13%)	2/13 (15%)
Ex-smoker	2/5 (40%)	1/8 (13%)	3/13 (23%)
Never smoker	2/5 (40%)	6/8 (75%)	8/13 (62%)
Missing	1 (17%)		1 (7%)
Total years smoking			
Valid Obs.	2	2	4
Mean (SD)	31.5 (12.0)	4.00 (0)	17.8 (17.3)
Median [Min, Max]	31.5 [23.0, 40.0]	4.00 [4.00, 4.00]	13.5 [4.00, 40.0]
Missing	4 (67%)	6 (75%)	10 (71%)
Number of cigarettes per day			
Valid Obs.	3	2	5
Mean (SD)	16.7 (12.6)	14.0 (8.49)	15.6 (9.96)
Median [Min, Max]	15.0 [5.00, 30.0]	14.0 [8.00, 20.0]	15.0 [5.00, 30.0]
Missing	3 (50%)	6 (75%)	9 (64%)
Years since quitting			
Valid Obs.	2	0	2
Mean (SD)	15.0 (7.07)		15.0 (7.07)
Median [Min, Max]	15.0 [10.0, 20.0]		15.0 [10.0, 20.0]
Missing	4 (67%)	8 (100%)	12 (86%)
Weeks since quitting (if less than a year)			
Valid Obs.	0	1	1
Mean (SD)		35.0 (NA)	35.0 (NA)
Median [Min, Max]		35.0 [35.0, 35.0]	35.0 [35.0, 35.0]
Missing	6 (100%)	7 (88%)	13 (93%)

Table 20 Medical History
Listing Population: Full (n = 15)

Participant ID	Group	Site	Medical condition	If yes, please specify	Start date	Ongoing	End date
10004	Active	N01	Hypothyroidism	T4 100 mcg od for 28 years - Partial thyroidectomy for Hashimoto 1991.	Unknown	Yes	
10004	Active	N01	Other Medical Condition	Past history of contact eczema of the hands. unknown cause. Last episode 6 months ago. Life-long and intermittent.	Unknown	Yes	
10006	Placebo	N01	Endocrine disorders	borderline polycystic ovaries	2014-06-01	Yes	
10006	Placebo	N01	Haematologic disorders	prev aneamia associated with menorrhagia TX low FE.	2016-07-01	No	2016-09-01
10036	Active	N01	Pulmonary disorders	Asthma	2022-02-07	Yes	
10036	Active	N01	Gastrointestinal disorders	Heamorrhoids	2021-10-01	Yes	
10038	Placebo	N01	Pulmonary disorders	bronchitis		No	
10038	Placebo	N01	Gastrointestinal disorders	Appendectomy aged 12		No	
10038	Placebo	N01	Neurologic disorders	headaches		Yes	
10038	Placebo	N01	Other Medical Condition	inguinal hernia	Unknown	No	
10038	Placebo	N01	Other Medical Condition	recently IX'd for some lumps .		Yes	
30011	Placebo	N03	Neurologic disorders	migraines, headaches		Yes	
30013	Active	N03	Gastrointestinal disorders	acid reflux	2018-08-31	Yes	
40005	Active	N04	Hyperthyroidism	Groves disease		No	
40005	Active	N04	Other Medical Condition	emergency C section	2001-09-29	No	2001-09-29
60004	Placebo	N06	Other Medical Condition	Hiatus Hernia on Omeprazole		Yes	
60004	Placebo	N06	Other Medical Condition	itchy feet on cetirizine, PRN. Urgency , nocturia, terminal dribbling		Yes	
60010	Active	N06	Gastrointestinal disorders	undergoing treatment c solifenacin, alfuzosin			
60014	Active	N06	Other Medical Condition	acid reflux	2015-09-15	No	2019-10-15
				Rhenaud's Disease diagnosed 25 yrs ago		Yes	

Table 21 Major surgery and infections
Listing Population: Full (n = 15)

Participant ID	Group	Site	Date of assessment	Did participant have any major surgery within the	Does participant have any planned surgery?	Did participant have any infections within the las
10004	Active	N01	2019-11-01	No	No	
10006	Placebo	N01	2019-11-08	No	No	
10019	Placebo	N01	2021-03-23	No	No	No
10036	Active	N01	2022-02-07	No	No	No
10038	Placebo	N01	2022-02-15	No	No	No
30002	Active	N03	2021-05-24	No	No	No
30006	Placebo	N03	2021-09-16	No	No	No
30011	Placebo	N03	2022-01-12	No	No	No
30013	Active	N03	2022-01-26	No	No	No
30015	Active	N03	2022-03-15	No	No	No
40005	Active	N04	2022-01-12	No	No	No
60004	Placebo	N06	2021-09-09	No	No	No
60009	Active	N06	2021-10-04	No	No	No
60010	Active	N06	2021-10-04	No	No	No
60014	Active	N06	2022-02-25	No	No	No

Table 22 Current anti-depressants
Listing Population: Full (n = 15)

Participant ID	Group	Site	Antidepressant (Generic name)	Duration of use	Actual dose (mg/d)	Response to treatment	Augmentation drug added?	Other medication	Vitamins/mineral supplements	Non-drug therapy	COVID-19 vaccine
10004	Active	N01	Sertraline	>=6 weeks	200	75 % to 100%	No	Yes	Yes	Yes	
10006	Placebo	N01	Sertraline	>=6 weeks	150	50 % to <75%	No	Yes	No	No	
10019	Placebo	N01	Duloxetine	>=6 weeks	120	50 % to <75%	No	Yes	Yes	No	
10036	Active	N01	Sertraline	>=6 weeks	100	<=25%	No	Yes	No	No	Yes
10038	Placebo	N01	Citalopram	>=6 weeks	35	50 % to <75%	No	Yes	Yes	No	No
30002	Active	N03	Citalopram	>=6 weeks	10	<=25%	No	No	Yes	No	
30006	Placebo	N03	Fluoxetine	>=6 weeks	20	<=25%	No	No	Yes	No	No
30011	Placebo	N03	Citalopram	>=6 weeks	30	50 % to <75%	No	Yes	No	No	Yes
30013	Active	N03	Vortioxetine	>=6 weeks	10	50 % to <75%	No	Yes	No	No	No
30015	Active	N03	Sertraline	>=6 weeks	100	50 % to <75%	No	Yes	Yes	No	No
40005	Active	N04	Sertraline	>=6 weeks	100	75 % to 100%	No	No	No	No	Yes
60004	Placebo	N06	Sertraline	>=6 weeks	200	26% to <50%	No	Yes	No	Yes	Yes
60009	Active	N06	Sertraline	>=6 weeks	100	50 % to <75%	No	Yes	No	No	No
60010	Active	N06	Citalopram	>=6 weeks	40	50 % to <75%	No	No	No	No	No
60014	Active	N06	Sertraline	>=6 weeks	200	26% to <50%	No	Yes	No	No	No

Table 23 Current past anti-depressants
Listing Population: Full (n = 15)

Participant ID	Group	Site	Antidepressant (Generic name)	Duration of use	Actual dose	Response to treatment	Augmentation drug added?	If yes, name of augmentation drug	Augmentation drug dose
10006	Placebo	N01	Citalopram	>=6 weeks		75 % to 100%	No		
10006	Placebo	N01	Mirtazipine	< 6 weeks		<=25%	No		
10019	Placebo	N01	Venlafaxine	>=6 weeks		50 % to <75%	No		
10036	Active	N01	Citalopram	>=6 weeks		<=25%	No		
30002	Active	N03	Citalopram	>=6 weeks	20	<=25%	No		
30011	Placebo	N03	Citalopram	< 6 weeks	10	50 % to <75%	No		
30013	Active	N03	Venlafaxine	>=6 weeks	150	<=25%	No		
30013	Active	N03	Sertraline	< 6 weeks		<=25%	No		
40005	Active	N04	Sertraline	>=6 weeks	100	75 % to 100%	Yes	Propranolol	20
60009	Active	N06	Unknown	< 6 weeks		<=25%	No		
60010	Active	N06	Citalopram	< 6 weeks	20	<=25%	No		

Section: Compliance
Table 24IMP Compliance review
Population: Full (n = 15)

Participant ID	Group	Date of participant's first dose	Total number of capsules taken	Compliance	Non-compliance reason
10004	Active	2019-11-20	58	Yes	Compliant
10019	Placebo	2021-06-03	61	Yes	Compliant
10036	Active	2022-04-16	29	No	Missed 7+ consecutive doses
10038	Placebo	2022-03-22	59	Yes	Compliant
30002	Active	2021-06-21	56	Yes	Compliant
30006	Placebo	2021-10-19	56	Yes	Compliant
30011	Placebo	2022-02-22	59	Yes	Compliant
30013	Active	2022-03-03	52	Yes	Compliant
30015	Active	2022-04-04	57	Yes	Compliant
40005	Active	2022-02-15	59	Yes	Compliant
60004	Placebo	2021-10-12	55	Yes	Compliant
60009	Active	2021-11-09	57	Yes	Compliant
60010	Active	2022-02-16	54	Yes	Compliant
60014	Active	2022-03-28	55	Yes	Compliant

Patient 10006 did not complete the form

Table 25 Non-compliance reasons
Listing Population: Full (n = 15)

Participant ID	Group	Site	Reason for non-compliance	CRF form reporting non-compliance
10006	1	N01	Participant met early IMP withdrawal criteria. Last visit completed while still on IMP D28 visit/ visit 2 Reason for patient withdrawal from IMP: Due to AE/SAE	End of IMP Treatment Withdrawal form IMP Treatment Phone Call 2 IMP kit Re-allocation
10036	2	N01	Patient did not continuing with trial drug. withdrawn from treatment from visit 2. 10036 stopped taking the IMP at the second visit (he carried on with study but stopped taking the IMP) so the IMP was not reallocated. Participant met early IMP withdrawal criteria. Last visit completed while still on IMP D28 visit/ visit 2 Reason for patient withdrawal from IMP: Positive Urine drug screen	End of IMP Treatment Withdrawal form IMP Treatment
30002	2	N03	On day 23 patient took 0 capsules. Reason: Unknown	IMP Compliance review
30013	2	N06	On day 25 patient took 0 capsules. Reason: Did not remember to take drug On day 44 patient took 0 capsules. Reason: Did not remember to take drug	IMP Compliance review IMP Compliance review
60004	1	N06	On day 52 patient took 0 capsules. Reason: Did not remember to take drug	IMP Compliance review

Section: Primary Endpoint
Table 26MADRS individual items
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
1. Reported sadness			
2		1/9 (11%)	1/15 (7%)
3	1/6 (17%)	2/9 (22%)	3/15 (20%)
4	3/6 (50%)	3/9 (33%)	6/15 (40%)
5	2/6 (33%)	3/9 (33%)	5/15 (33%)
2. Apparent sadness			
0		1/9 (11%)	1/15 (7%)
2	2/6 (33%)		2/15 (13%)
3	1/6 (17%)	4/9 (44%)	5/15 (33%)
4	3/6 (50%)	4/9 (44%)	7/15 (47%)
3. Inner Tension			
1	1/6 (17%)	1/9 (11%)	2/15 (13%)
2	1/6 (17%)		1/15 (7%)
3	3/6 (50%)	3/9 (33%)	6/15 (40%)
4	1/6 (17%)	4/9 (44%)	5/15 (33%)
5		1/9 (11%)	1/15 (7%)
4. Reduced sleep			
0		3/9 (33%)	3/15 (20%)
1	1/6 (17%)		1/15 (7%)
2	2/6 (33%)	1/9 (11%)	3/15 (20%)
3		4/9 (44%)	4/15 (27%)
4	1/6 (17%)	1/9 (11%)	2/15 (13%)
5	2/6 (33%)		2/15 (13%)
5. Reduced appetite			
0	3/6 (50%)	3/9 (33%)	6/15 (40%)
1	2/6 (33%)		2/15 (13%)
3	1/6 (17%)	6/9 (67%)	7/15 (47%)
6. Concentration Difficulties			
2	1/6 (17%)	1/9 (11%)	2/15 (13%)
3	1/6 (17%)	3/9 (33%)	4/15 (27%)
4	4/6 (67%)	5/9 (56%)	9/15 (60%)
7. Lassitude			
2	2/6 (33%)	2/9 (22%)	4/15 (27%)
3	1/6 (17%)	2/9 (22%)	3/15 (20%)
4	3/6 (50%)	5/9 (56%)	8/15 (53%)
8. Inability to Feel			
1	1/6 (17%)		1/15 (7%)
2	1/6 (17%)	2/9 (22%)	3/15 (20%)
3	3/6 (50%)	5/9 (56%)	8/15 (53%)
4	1/6 (17%)	2/9 (22%)	3/15 (20%)
9. Pessimistic Thoughts			
0	1/6 (17%)	1/9 (11%)	2/15 (13%)
1	1/6 (17%)		1/15 (7%)
2		1/9 (11%)	1/15 (7%)
3	2/6 (33%)	2/9 (22%)	4/15 (27%)
4	2/6 (33%)	5/9 (56%)	7/15 (47%)
10. Suicidal Thoughts			
0	2/6 (33%)	2/9 (22%)	4/15 (27%)
1	2/6 (33%)	3/9 (33%)	5/15 (33%)
2	1/6 (17%)	2/9 (22%)	3/15 (20%)
3		2/9 (22%)	2/15 (13%)
4	1/6 (17%)		1/15 (7%)
Total Score (Derived)			
Valid Obs.	6	9	15

Variable	Placebo	Active	Total
Mean (SD)	27.2 (4.22)	28.8 (7.84)	28.1 (6.49)
Median [Min, Max]	26.0 [23.0, 35.0]	32.0 [12.0, 36.0]	28.0 [12.0, 36.0]
Visit = Visit 2			
Observation	6	9	15
1. Reported sadness			
0		1/9 (11%)	1/15 (7%)
1	1/6 (17%)	1/9 (11%)	2/15 (13%)
2	1/6 (17%)	1/9 (11%)	2/15 (13%)
3		3/9 (33%)	3/15 (20%)
4	3/6 (50%)	2/9 (22%)	5/15 (33%)
5	1/6 (17%)	1/9 (11%)	2/15 (13%)
2. Apparent sadness			
0	1/6 (17%)	1/9 (11%)	2/15 (13%)
1		1/9 (11%)	1/15 (7%)
2	1/6 (17%)	3/9 (33%)	4/15 (27%)
3	1/6 (17%)	3/9 (33%)	4/15 (27%)
4	3/6 (50%)	1/9 (11%)	4/15 (27%)
3. Inner Tension			
0	1/6 (17%)	1/9 (11%)	2/15 (13%)
2	2/6 (33%)	1/9 (11%)	3/15 (20%)
3		5/9 (56%)	5/15 (33%)
4	2/6 (33%)	1/9 (11%)	3/15 (20%)
5	1/6 (17%)	1/9 (11%)	2/15 (13%)
4. Reduced sleep			
0	1/6 (17%)	3/9 (33%)	4/15 (27%)
1	1/6 (17%)		1/15 (7%)
2	2/6 (33%)	1/9 (11%)	3/15 (20%)
3		4/9 (44%)	4/15 (27%)
4	1/6 (17%)	1/9 (11%)	2/15 (13%)
5	1/6 (17%)		1/15 (7%)
5. Reduced appetite			
0	4/6 (67%)	6/9 (67%)	10/15 (67%)
1	1/6 (17%)		1/15 (7%)
2		1/9 (11%)	1/15 (7%)
3	1/6 (17%)	2/9 (22%)	3/15 (20%)
6. Concentration Difficulties			
0		2/9 (22%)	2/15 (13%)
1	1/6 (17%)		1/15 (7%)
2	1/6 (17%)		1/15 (7%)
3	1/6 (17%)	2/9 (22%)	3/15 (20%)
4	3/6 (50%)	5/9 (56%)	8/15 (53%)
7. Lassitude			
0	1/6 (17%)	2/9 (22%)	3/15 (20%)
1		1/9 (11%)	1/15 (7%)
2		2/9 (22%)	2/15 (13%)
3	2/6 (33%)	1/9 (11%)	3/15 (20%)
4	2/6 (33%)	3/9 (33%)	5/15 (33%)
5	1/6 (17%)		1/15 (7%)
8. Inability to Feel			
0	1/6 (17%)	2/9 (22%)	3/15 (20%)
2	2/6 (33%)	2/9 (22%)	4/15 (27%)
3	1/6 (17%)	5/9 (56%)	6/15 (40%)
4	2/6 (33%)		2/15 (13%)
9. Pessimistic Thoughts			
0	1/6 (17%)	2/9 (22%)	3/15 (20%)
1	1/6 (17%)		1/15 (7%)
2	2/6 (33%)	2/9 (22%)	4/15 (27%)
3	1/6 (17%)	4/9 (44%)	5/15 (33%)
4	1/6 (17%)	1/9 (11%)	2/15 (13%)

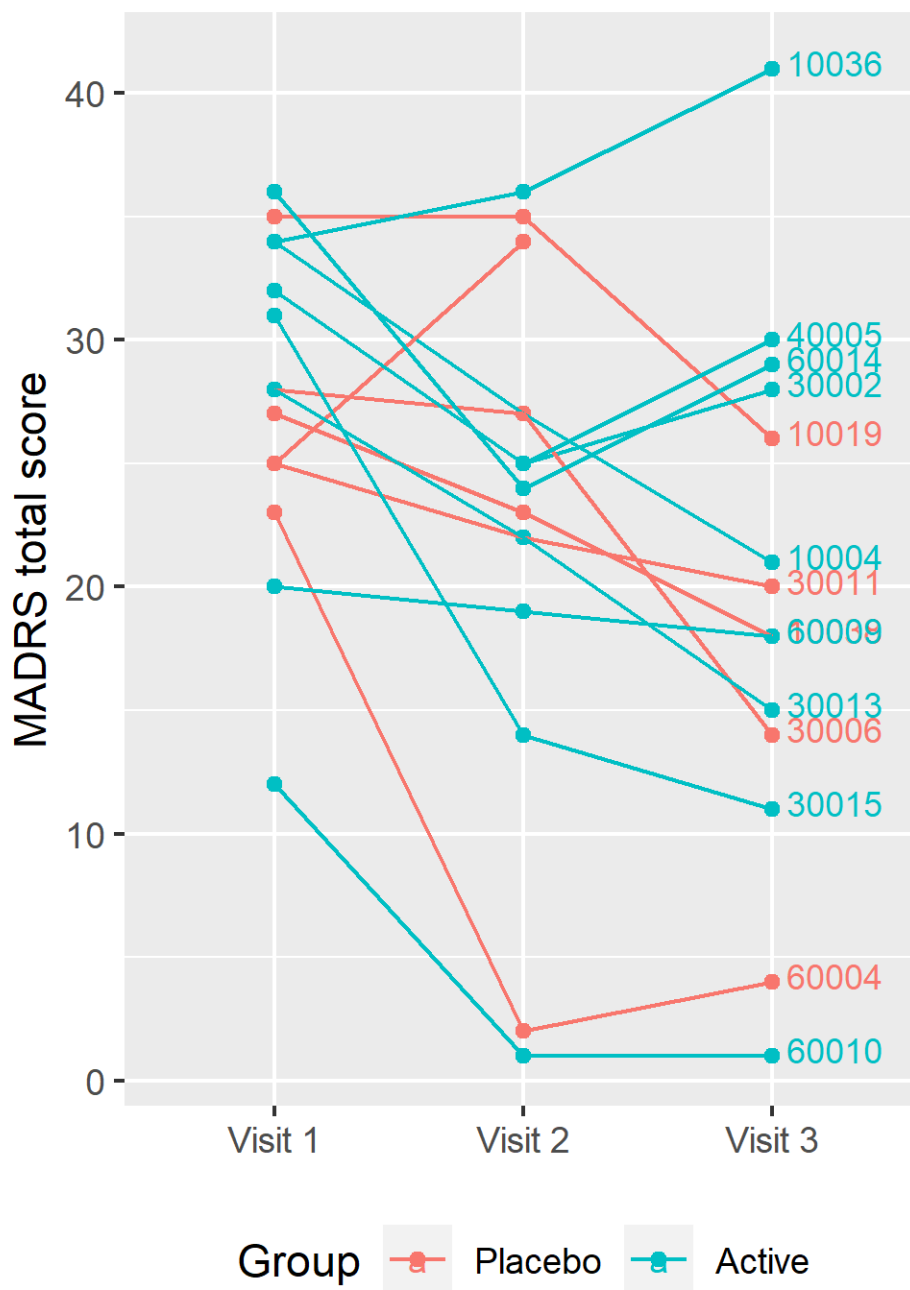
Variable	Placebo	Active	Total
10. Suicidal Thoughts			
0	2/6 (33%)	1/9 (11%)	3/15 (20%)
1	3/6 (50%)	5/9 (56%)	8/15 (53%)
2		3/9 (33%)	3/15 (20%)
4	1/6 (17%)		1/15 (7%)
Total Score (Derived)			
Valid Obs.	6	9	15
Mean (SD)	23.8 (12.0)	21.4 (9.71)	22.4 (10.3)
Median [Min, Max]	25.0 [2.00, 35.0]	24.0 [1.00, 36.0]	24.0 [1.00, 36.0]
Visit = Visit 3			
Observation	5	9	14
1. Reported sadness			
0	1/5 (20%)	1/9 (11%)	2/14 (14%)
1		2/9 (22%)	2/14 (14%)
2	1/5 (20%)	1/9 (11%)	2/14 (14%)
3	3/5 (60%)	1/9 (11%)	4/14 (29%)
4		1/9 (11%)	1/14 (7%)
5		3/9 (33%)	3/14 (21%)
2. Apparent sadness			
0	1/5 (20%)	2/9 (22%)	3/14 (21%)
1	1/5 (20%)	1/9 (11%)	2/14 (14%)
2	1/5 (20%)		1/14 (7%)
3	2/5 (40%)	3/9 (33%)	5/14 (36%)
4		3/9 (33%)	3/14 (21%)
3. Inner Tension			
0	1/5 (20%)	1/9 (11%)	2/14 (14%)
2	1/5 (20%)	2/9 (22%)	3/14 (21%)
3	2/5 (40%)	3/9 (33%)	5/14 (36%)
4	1/5 (20%)	3/9 (33%)	4/14 (29%)
4. Reduced sleep			
0	1/5 (20%)	4/9 (44%)	5/14 (36%)
2	2/5 (40%)	2/9 (22%)	4/14 (29%)
3	1/5 (20%)	1/9 (11%)	2/14 (14%)
4		2/9 (22%)	2/14 (14%)
5	1/5 (20%)		1/14 (7%)
5. Reduced appetite			
0	4/5 (80%)	5/9 (56%)	9/14 (64%)
1	1/5 (20%)	1/9 (11%)	2/14 (14%)
3		1/9 (11%)	1/14 (7%)
4		1/9 (11%)	1/14 (7%)
5		1/9 (11%)	1/14 (7%)
6. Concentration Difficulties			
0	1/5 (20%)	1/9 (11%)	2/14 (14%)
2		2/9 (22%)	2/14 (14%)
3	4/5 (80%)	4/9 (44%)	8/14 (57%)
4		1/9 (11%)	1/14 (7%)
5		1/9 (11%)	1/14 (7%)
7. Lassitude			
0	1/5 (20%)	3/9 (33%)	4/14 (29%)
1	2/5 (40%)		2/14 (14%)
2		2/9 (22%)	2/14 (14%)
3	2/5 (40%)	3/9 (33%)	5/14 (36%)
4		1/9 (11%)	1/14 (7%)
8. Inability to Feel			
0		2/9 (22%)	2/14 (14%)
1	2/5 (40%)	1/9 (11%)	3/14 (21%)
2	2/5 (40%)	2/9 (22%)	4/14 (29%)
3	1/5 (20%)	2/9 (22%)	3/14 (21%)
4		2/9 (22%)	2/14 (14%)

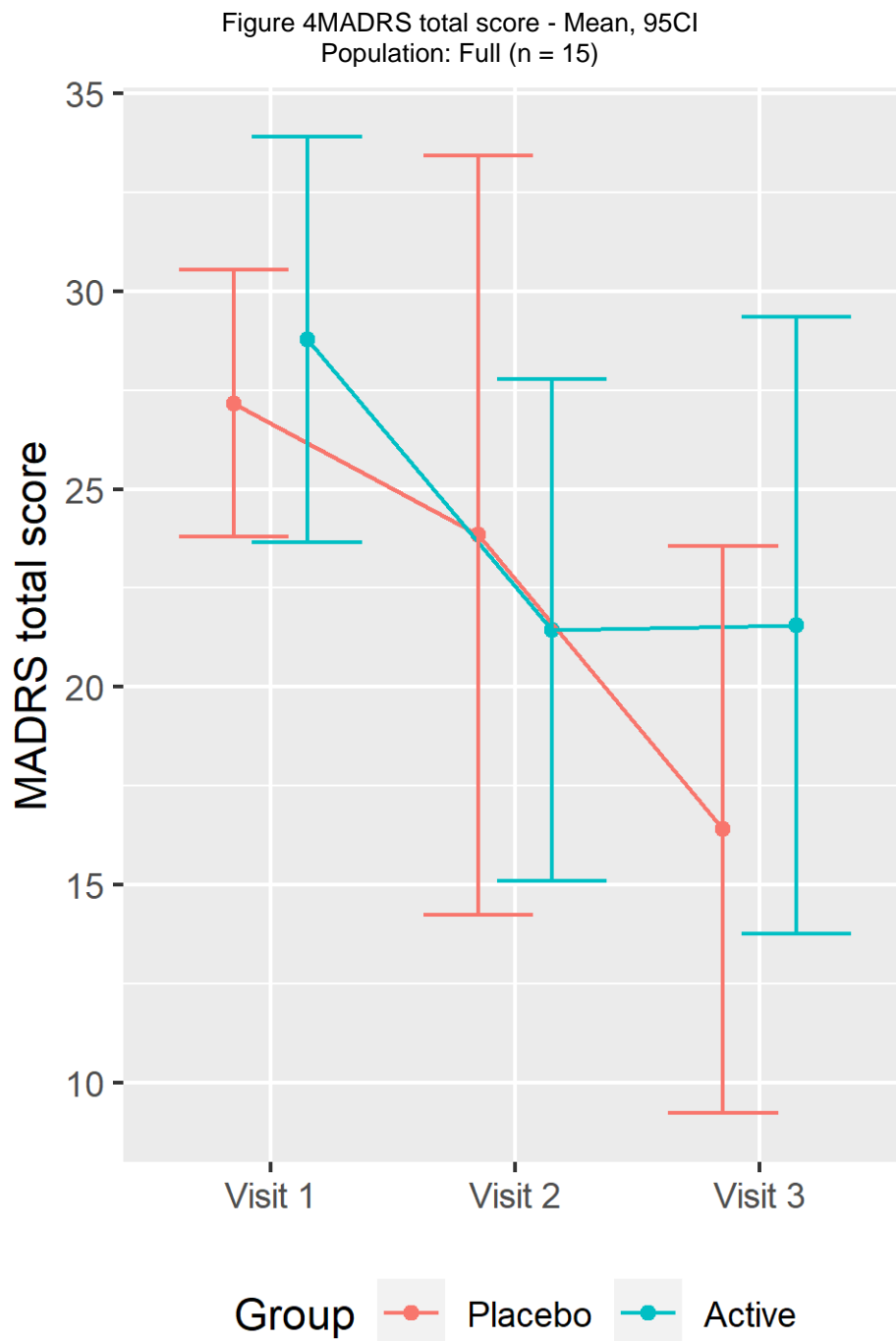
Variable	Placebo	Active	Total
9. Pessimistic Thoughts			
0	2/5 (40%)	2/9 (22%)	4/14 (29%)
2	2/5 (40%)	2/9 (22%)	4/14 (29%)
3	1/5 (20%)	2/9 (22%)	3/14 (21%)
4		3/9 (33%)	3/14 (21%)
10. Suicidal Thoughts			
0	4/5 (80%)	2/9 (22%)	6/14 (43%)
1	1/5 (20%)	4/9 (44%)	5/14 (36%)
2		3/9 (33%)	3/14 (21%)
Total Score (Derived)			
Valid Obs.	5	9	14
Mean (SD)	16.4 (8.17)	21.6 (11.9)	19.7 (10.7)
Median [Min, Max]	18.0 [4.00, 26.0]	21.0 [1.00, 41.0]	19.0 [1.00, 41.0]

Table 27MADRS total score
Population: Full (n = 15)

Participant ID	Group	Visit 1	Visit 2	Visit 3	Change from baseline
10004	Active	34	27	21	-13
10006	Placebo	25	34	NA	NA
10019	Placebo	35	35	26	-9
10036	Active	34	36	41	7
10038	Placebo	27	23	18	-9
30002	Active	32	25	28	-4
30006	Placebo	28	27	14	-14
30011	Placebo	25	22	20	-5
30013	Active	28	22	15	-13
30015	Active	31	14	11	-20
40005	Active	32	25	30	-2
60004	Placebo	23	2	4	-19
60009	Active	20	19	18	-2
60010	Active	12	1	1	-11
60014	Active	36	24	29	-7

Figure 3MADRS total score - Line plot
Line plot Population: Full (n = 15)





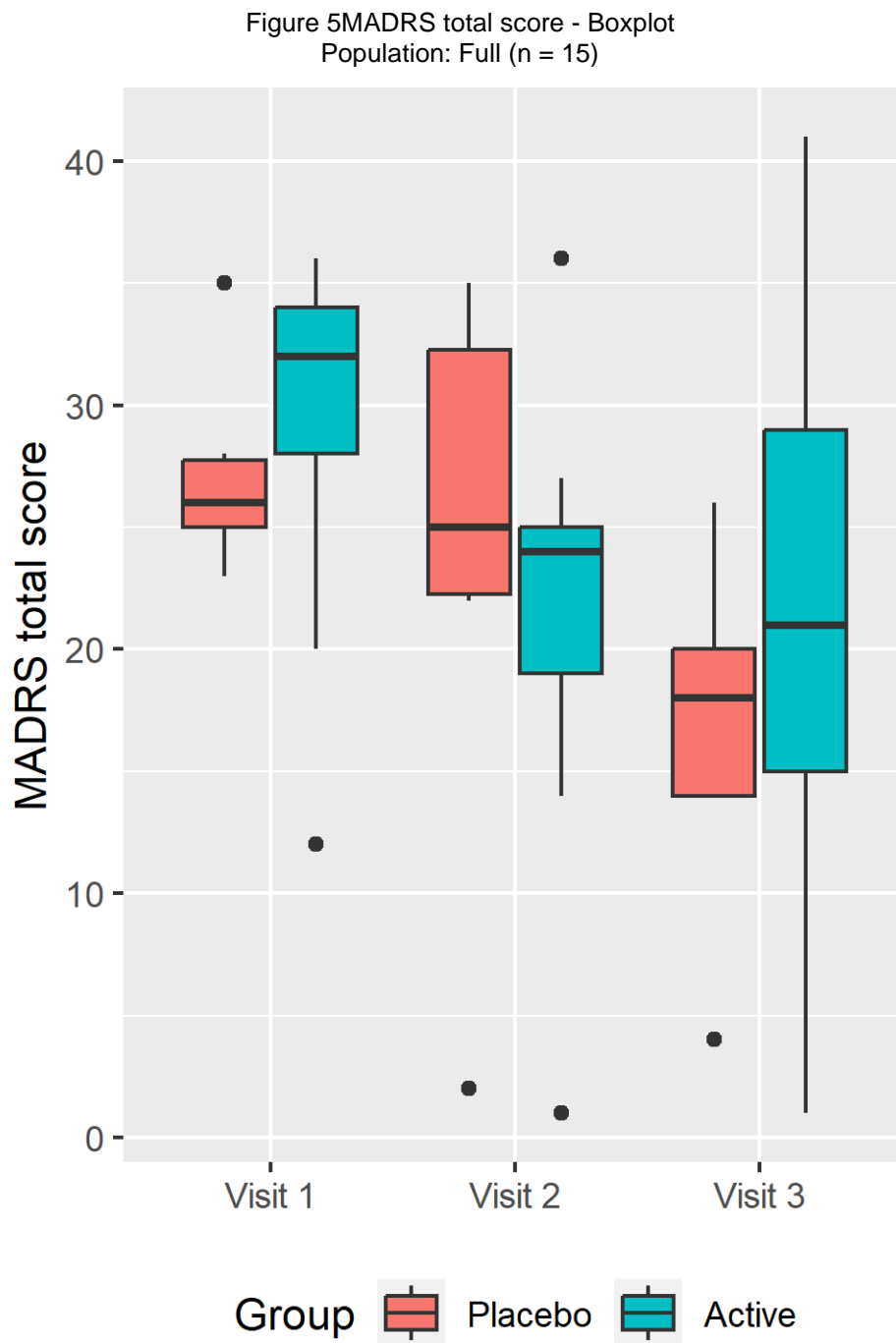
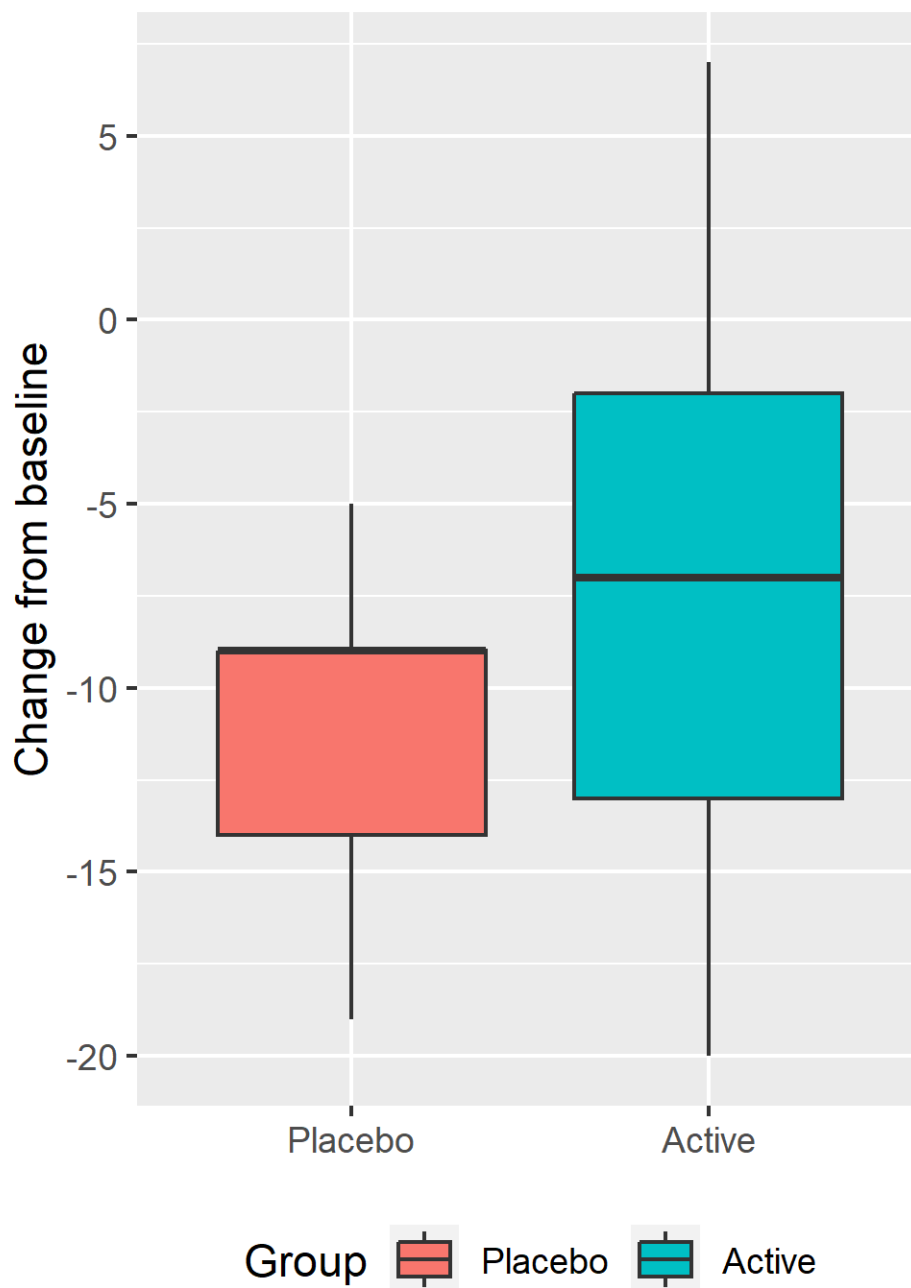


Table 28MADRAS score - Change from baseline
Population: Full (n = 15)

Variable	Placebo	Active	Total
Observation	6	9	15
Change from baseline			
Valid Obs.	5	9	14
Mean (SD)	-11.2 (5.40)	-7.22 (8.00)	-8.64 (7.23)
Median [Min, Max]	-9.00 [-19.0, -5.00]	-7.00 [-20.0, 7.00]	-9.00 [-20.0, 7.00]
Missing	1 (17%)		1 (7%)

Figure 6MADRAS score - Change from baseline
Boxplot Population: Full (n = 15)



Section: PROMS
Table 29 Perceived Stress Scales
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
Been upset by something happening unexpectedly			
Almost Never	1/6 (17%)	1/9 (11%)	2/15 (13%)
Sometimes	4/6 (67%)	1/9 (11%)	5/15 (33%)
Fairly often	1/6 (17%)	6/9 (67%)	7/15 (47%)
Very often		1/9 (11%)	1/15 (7%)
Felt that you were unable to control the important			
Never	1/6 (17%)		1/15 (7%)
Almost never		1/9 (11%)	1/15 (7%)
Sometimes	3/6 (50%)	2/9 (22%)	5/15 (33%)
Fairly often	2/6 (33%)	2/9 (22%)	4/15 (27%)
Very often		4/9 (44%)	4/15 (27%)
Felt nervous and stressed?			
Sometimes	1/6 (17%)		1/15 (7%)
Fairly Often	4/6 (67%)	3/9 (33%)	7/15 (47%)
Very often	1/6 (17%)	6/9 (67%)	7/15 (47%)
Felt that things were going your way?			
Almost never	4/6 (67%)	2/9 (22%)	6/15 (40%)
Sometimes	2/6 (33%)	4/9 (44%)	6/15 (40%)
Fairly Often		2/9 (22%)	2/15 (13%)
Very often		1/9 (11%)	1/15 (7%)
Felt that things were going your way?			
Never		1/9 (11%)	1/15 (7%)
Almost never	3/6 (50%)	6/9 (67%)	9/15 (60%)
Sometimes	3/6 (50%)	2/9 (22%)	5/15 (33%)
Found that you could not cope with all the things			
Almost never		1/9 (11%)	1/15 (7%)
Sometimes	2/6 (33%)	1/9 (11%)	3/15 (20%)
Fairly often	4/6 (67%)	4/9 (44%)	8/15 (53%)
Very often		3/9 (33%)	3/15 (20%)
Been able to control irritations in your life?			
Never		2/9 (22%)	2/15 (13%)
Almost never	1/6 (17%)	3/9 (33%)	4/15 (27%)
Sometimes	5/6 (83%)	3/9 (33%)	8/15 (53%)
Fairly often		1/9 (11%)	1/15 (7%)
Felt that you were on top of things?			
Never	1/6 (17%)	4/9 (44%)	5/15 (33%)
Almost never	4/6 (67%)	3/9 (33%)	7/15 (47%)
Sometimes		2/9 (22%)	2/15 (13%)
Fairly often	1/6 (17%)		1/15 (7%)
Been angered because of things outside your contr			
Never		1/9 (11%)	1/15 (7%)
Almost never		3/9 (33%)	3/15 (20%)
Sometimes	2/6 (33%)	1/9 (11%)	3/15 (20%)
Fairly often	4/6 (67%)	1/9 (11%)	5/15 (33%)
Very often		3/9 (33%)	3/15 (20%)
Felt difficulties were piling up so high you could			
Almost never	1/6 (17%)		1/15 (7%)
Sometimes	3/6 (50%)	3/9 (33%)	6/15 (40%)
Fairly often	2/6 (33%)	1/9 (11%)	3/15 (20%)
Very often		5/9 (56%)	5/15 (33%)
Visit = Visit 2			
Observation	6	9	15
Been upset by something happening unexpectedly			
Almost Never	1/5 (20%)		1/14 (7%)

Variable	Placebo	Active	Total
Sometimes	2/5 (40%)	4/9 (44%)	6/14 (43%)
Fairly often	1/5 (20%)	5/9 (56%)	6/14 (43%)
Very often	1/5 (20%)		1/14 (7%)
Missing	1 (17%)		1 (7%)
Felt that you were unable to control the important			
Almost never		1/9 (11%)	1/14 (7%)
Sometimes	2/5 (40%)	3/9 (33%)	5/14 (36%)
Fairly often	2/5 (40%)	2/9 (22%)	4/14 (29%)
Very often	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
Felt nervous and stressed?			
Sometimes	2/5 (40%)	1/9 (11%)	3/14 (21%)
Fairly Often	1/5 (20%)	3/9 (33%)	4/14 (29%)
Very often	2/5 (40%)	5/9 (56%)	7/14 (50%)
Missing	1 (17%)		1 (7%)
Felt that things were going your way?			
Never		1/9 (11%)	1/14 (7%)
Almost never	1/5 (20%)	1/9 (11%)	2/14 (14%)
Sometimes	3/5 (60%)	3/9 (33%)	6/14 (43%)
Fairly Often	1/5 (20%)	3/9 (33%)	4/14 (29%)
Very often		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
Felt that things were going your way?			
Almost never	4/5 (80%)	3/9 (33%)	7/14 (50%)
Sometimes		5/9 (56%)	5/14 (36%)
Fairly often	1/5 (20%)	1/9 (11%)	2/14 (14%)
Missing	1 (17%)		1 (7%)
Found that you could not cope with all the things			
Almost never	2/5 (40%)		2/14 (14%)
Sometimes		3/9 (33%)	3/14 (21%)
Fairly often	2/5 (40%)	2/9 (22%)	4/14 (29%)
Very often	1/5 (20%)	4/9 (44%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Been able to control irritations in your life?			
Never		2/9 (22%)	2/14 (14%)
Almost never	2/5 (40%)	4/9 (44%)	6/14 (43%)
Sometimes	3/5 (60%)	2/9 (22%)	5/14 (36%)
Fairly often		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
Felt that you were on top of things?			
Never	1/5 (20%)	4/9 (44%)	5/14 (36%)
Almost never	2/5 (40%)	1/9 (11%)	3/14 (21%)
Sometimes	1/5 (20%)	1/9 (11%)	2/14 (14%)
Fairly often	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
Been angered because of things outside your contr			
Never	1/5 (20%)		1/14 (7%)
Almost never		1/9 (11%)	1/14 (7%)
Sometimes		4/9 (44%)	4/14 (29%)
Fairly often	3/5 (60%)	2/9 (22%)	5/14 (36%)
Very often	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
Felt difficulties were piling up so high you could			
Almost never	2/5 (40%)	2/9 (22%)	4/14 (29%)
Sometimes	1/5 (20%)	2/9 (22%)	3/14 (21%)
Fairly often	1/5 (20%)	1/9 (11%)	2/14 (14%)
Very often	1/5 (20%)	4/9 (44%)	5/14 (36%)
Missing	1 (17%)		1 (7%)

Visit = Visit 3

Variable	Placebo	Active	Total
Observation	5	9	14
Been upset by something happening unexpectedly			
Almost Never	1/5 (20%)	2/9 (22%)	3/14 (21%)
Sometimes	3/5 (60%)	3/9 (33%)	6/14 (43%)
Fairly often		3/9 (33%)	3/14 (21%)
Very often	1/5 (20%)	1/9 (11%)	2/14 (14%)
Felt that you were unable to control the important			
Never	1/5 (20%)		1/14 (7%)
Almost never	1/5 (20%)	1/9 (11%)	2/14 (14%)
Sometimes	1/5 (20%)		1/14 (7%)
Fairly often	1/5 (20%)	3/9 (33%)	4/14 (29%)
Very often	1/5 (20%)	5/9 (56%)	6/14 (43%)
Felt nervous and stressed?			
Almost never	1/5 (20%)		1/14 (7%)
Sometimes	1/5 (20%)	1/9 (11%)	2/14 (14%)
Fairly Often	1/5 (20%)	3/9 (33%)	4/14 (29%)
Very often	2/5 (40%)	5/9 (56%)	7/14 (50%)
Felt that things were going your way?			
Almost never	1/5 (20%)	4/8 (50%)	5/13 (38%)
Sometimes	2/5 (40%)	2/8 (25%)	4/13 (31%)
Fairly Often	1/5 (20%)	2/8 (25%)	3/13 (23%)
Very often	1/5 (20%)		1/13 (8%)
Missing		1 (11%)	1 (7%)
Felt that things were going your way?			
Never		2/9 (22%)	2/14 (14%)
Almost never	2/5 (40%)	3/9 (33%)	5/14 (36%)
Sometimes	2/5 (40%)	3/9 (33%)	5/14 (36%)
Fairly often		1/9 (11%)	1/14 (7%)
Very often	1/5 (20%)		1/14 (7%)
Found that you could not cope with all the things			
Never	1/5 (20%)		1/14 (7%)
Almost never	1/5 (20%)	2/9 (22%)	3/14 (21%)
Sometimes	2/5 (40%)	1/9 (11%)	3/14 (21%)
Fairly often		3/9 (33%)	3/14 (21%)
Very often	1/5 (20%)	3/9 (33%)	4/14 (29%)
Been able to control irritations in your life?			
Never		2/9 (22%)	2/14 (14%)
Almost never		2/9 (22%)	2/14 (14%)
Sometimes	4/5 (80%)	3/9 (33%)	7/14 (50%)
Fairly often		2/9 (22%)	2/14 (14%)
Very often	1/5 (20%)		1/14 (7%)
Felt that you were on top of things?			
Never		3/9 (33%)	3/14 (21%)
Almost never	3/5 (60%)	2/9 (22%)	5/14 (36%)
Sometimes	1/5 (20%)	2/9 (22%)	3/14 (21%)
Fairly often		2/9 (22%)	2/14 (14%)
Very often	1/5 (20%)		1/14 (7%)
Been angered because of things outside your contr			
Never	1/5 (20%)	2/9 (22%)	3/14 (21%)
Almost never		1/9 (11%)	1/14 (7%)
Sometimes	2/5 (40%)	2/9 (22%)	4/14 (29%)
Fairly often	2/5 (40%)	2/9 (22%)	4/14 (29%)
Very often		2/9 (22%)	2/14 (14%)
Felt difficulties were piling up so high you could			
Never	1/5 (20%)		1/14 (7%)
Almost never	1/5 (20%)	2/9 (22%)	3/14 (21%)
Sometimes	1/5 (20%)	2/9 (22%)	3/14 (21%)
Fairly often	2/5 (40%)	1/9 (11%)	3/14 (21%)
Very often		4/9 (44%)	4/14 (29%)

Table 30 Generalized Anxiety Disorder 7 (GAD-7)
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
Feeling nervous, anxious or on edge			
Several days	3/6 (50%)	1/9 (11%)	4/15 (27%)
More than half the days	1/6 (17%)	2/9 (22%)	3/15 (20%)
Nearly every day	2/6 (33%)	6/9 (67%)	8/15 (53%)
Not being able to stop or control worrying			
Several days	2/6 (33%)	3/9 (33%)	5/15 (33%)
More than half the days	3/6 (50%)	2/9 (22%)	5/15 (33%)
Nearly every day	1/6 (17%)	4/9 (44%)	5/15 (33%)
Worrying too much about different things			
Several days		2/9 (22%)	2/15 (13%)
More than half the days	4/6 (67%)	2/9 (22%)	6/15 (40%)
Nearly every day	2/6 (33%)	5/9 (56%)	7/15 (47%)
Trouble relaxing			
Several days	3/6 (50%)	1/9 (11%)	4/15 (27%)
More than half the days	2/6 (33%)	3/9 (33%)	5/15 (33%)
Nearly every day	1/6 (17%)	5/9 (56%)	6/15 (40%)
Being so restless that it is hard to sit still			
Not at all	4/6 (67%)	2/9 (22%)	6/15 (40%)
Several days		1/9 (11%)	1/15 (7%)
More than half the days	1/6 (17%)	2/9 (22%)	3/15 (20%)
Nearly every day	1/6 (17%)	4/9 (44%)	5/15 (33%)
Becoming easily annoyed or irritable			
Not at all		2/9 (22%)	2/15 (13%)
Several days	5/6 (83%)	2/9 (22%)	7/15 (47%)
More than half the days		1/9 (11%)	1/15 (7%)
Nearly every day	1/6 (17%)	4/9 (44%)	5/15 (33%)
Feeling afraid as if something awful might happen			
Not at all	5/6 (83%)	3/9 (33%)	8/15 (53%)
Several days		2/9 (22%)	2/15 (13%)
More than half the days		2/9 (22%)	2/15 (13%)
Nearly every day	1/6 (17%)	2/9 (22%)	3/15 (20%)
Visit = Visit 2			
Observation	6	9	15
Feeling nervous, anxious or on edge			
Not at all	1/5 (20%)	1/9 (11%)	2/14 (14%)
Several days	1/5 (20%)	4/9 (44%)	5/14 (36%)
More than half the days	1/5 (20%)	1/9 (11%)	2/14 (14%)
Nearly every day	2/5 (40%)	3/9 (33%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Not being able to stop or control worrying			
Not at all	1/5 (20%)	2/9 (22%)	3/14 (21%)
Several days	2/5 (40%)	2/9 (22%)	4/14 (29%)
More than half the days		2/9 (22%)	2/14 (14%)
Nearly every day	2/5 (40%)	3/9 (33%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Worrying too much about different things			
Not at all		1/9 (11%)	1/14 (7%)
Several days	2/5 (40%)	2/9 (22%)	4/14 (29%)
More than half the days	1/5 (20%)	3/9 (33%)	4/14 (29%)
Nearly every day	2/5 (40%)	3/9 (33%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Trouble relaxing			
Not at all		1/9 (11%)	1/14 (7%)
Several days	2/5 (40%)	1/9 (11%)	3/14 (21%)
More than half the days	2/5 (40%)	3/9 (33%)	5/14 (36%)

Variable	Placebo	Active	Total
Nearly every day	1/5 (20%)	4/9 (44%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Being so restless that it is hard to sit still			
Not at all	3/5 (60%)	2/9 (22%)	5/14 (36%)
Several days	1/5 (20%)	3/9 (33%)	4/14 (29%)
More than half the days		2/9 (22%)	2/14 (14%)
Nearly every day	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
Becoming easily annoyed or irritable			
Not at all	2/5 (40%)	1/9 (11%)	3/14 (21%)
Several days	2/5 (40%)	3/9 (33%)	5/14 (36%)
More than half the days		3/9 (33%)	3/14 (21%)
Nearly every day	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
Feeling afraid as if something awful might happen			
Not at all	4/5 (80%)	3/9 (33%)	7/14 (50%)
Several days		4/9 (44%)	4/14 (29%)
More than half the days		2/9 (22%)	2/14 (14%)
Nearly every day	1/5 (20%)		1/14 (7%)
Missing	1 (17%)		1 (7%)
Visit = Visit 3			
Observation	5	9	14
Feeling nervous, anxious or on edge			
Not at all	1/5 (20%)	1/9 (11%)	2/14 (14%)
Several days	2/5 (40%)	1/9 (11%)	3/14 (21%)
More than half the days	1/5 (20%)	3/9 (33%)	4/14 (29%)
Nearly every day	1/5 (20%)	4/9 (44%)	5/14 (36%)
Not being able to stop or control worrying			
Not at all	1/5 (20%)	1/9 (11%)	2/14 (14%)
Several days	3/5 (60%)	3/9 (33%)	6/14 (43%)
More than half the days		1/9 (11%)	1/14 (7%)
Nearly every day	1/5 (20%)	4/9 (44%)	5/14 (36%)
Worrying too much about different things			
Not at all	1/5 (20%)	1/9 (11%)	2/14 (14%)
Several days	3/5 (60%)	3/9 (33%)	6/14 (43%)
More than half the days		1/9 (11%)	1/14 (7%)
Nearly every day	1/5 (20%)	4/9 (44%)	5/14 (36%)
Trouble relaxing			
Not at all	1/5 (20%)	1/9 (11%)	2/14 (14%)
Several days	3/5 (60%)	3/9 (33%)	6/14 (43%)
More than half the days		1/9 (11%)	1/14 (7%)
Nearly every day	1/5 (20%)	4/9 (44%)	5/14 (36%)
Being so restless that it is hard to sit still			
Not at all	3/5 (60%)	2/9 (22%)	5/14 (36%)
Several days	1/5 (20%)	3/9 (33%)	4/14 (29%)
More than half the days		2/9 (22%)	2/14 (14%)
Nearly every day	1/5 (20%)	2/9 (22%)	3/14 (21%)
Becoming easily annoyed or irritable			
Not at all	1/5 (20%)	2/9 (22%)	3/14 (21%)
Several days	3/5 (60%)	2/9 (22%)	5/14 (36%)
More than half the days	1/5 (20%)	1/9 (11%)	2/14 (14%)
Nearly every day		4/9 (44%)	4/14 (29%)
Feeling afraid as if something awful might happen			
Not at all	3/5 (60%)	2/9 (22%)	5/14 (36%)
Several days	2/5 (40%)	1/9 (11%)	3/14 (21%)
More than half the days		2/9 (22%)	2/14 (14%)
Nearly every day		4/9 (44%)	4/14 (29%)

Table 31 Chalder Fatigue Questionnaire
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
Do you have problems with tiredness?			
No more than usual	2/6 (33%)	1/9 (11%)	3/15 (20%)
More than usual	3/6 (50%)	3/9 (33%)	6/15 (40%)
Much more than usual	1/6 (17%)	5/9 (56%)	6/15 (40%)
Do you need to rest more?			
No more than usual	2/6 (33%)	3/9 (33%)	5/15 (33%)
More than usual	3/6 (50%)	1/9 (11%)	4/15 (27%)
Much more than usual	1/6 (17%)	5/9 (56%)	6/15 (40%)
Do you feel sleepy or drowsy?			
No more than usual	2/6 (33%)	2/9 (22%)	4/15 (27%)
More than usual	3/6 (50%)	2/9 (22%)	5/15 (33%)
Much more than usual	1/6 (17%)	5/9 (56%)	6/15 (40%)
Do you have problems starting things?			
No more than usual	1/6 (17%)	1/9 (11%)	2/15 (13%)
More than usual	4/6 (67%)	4/9 (44%)	8/15 (53%)
Much more than usual	1/6 (17%)	4/9 (44%)	5/15 (33%)
Do you lack energy?			
No more than usual	2/6 (33%)	1/9 (11%)	3/15 (20%)
More than usual	3/6 (50%)	2/9 (22%)	5/15 (33%)
Much more than usual	1/6 (17%)	6/9 (67%)	7/15 (47%)
Do you have less strength in your muscles?			
Less than usual		1/9 (11%)	1/15 (7%)
No more than usual	4/6 (67%)	5/9 (56%)	9/15 (60%)
More than usual	1/6 (17%)	2/9 (22%)	3/15 (20%)
Much more than usual	1/6 (17%)	1/9 (11%)	2/15 (13%)
Do you feel weak?			
Less than usual		1/9 (11%)	1/15 (7%)
No more than usual	3/6 (50%)	5/9 (56%)	8/15 (53%)
More than usual	2/6 (33%)	3/9 (33%)	5/15 (33%)
Much more than usual	1/6 (17%)		1/15 (7%)
Do you have difficulties concentrating?			
No more than usual	2/6 (33%)	3/9 (33%)	5/15 (33%)
More than usual	1/6 (17%)	3/9 (33%)	4/15 (27%)
Much more than usual	3/6 (50%)	3/9 (33%)	6/15 (40%)
Do you make slips of the tongue when speaking?			
Less than usual		1/9 (11%)	1/15 (7%)
No more than usual	4/6 (67%)	3/9 (33%)	7/15 (47%)
More than usual	2/6 (33%)	3/9 (33%)	5/15 (33%)
Much more than usual		2/9 (22%)	2/15 (13%)
Do you find it more difficult to find the right words?			
Less than usual		2/9 (22%)	2/15 (13%)
No more than usual	3/6 (50%)	1/9 (11%)	4/15 (27%)
More than usual	3/6 (50%)	5/9 (56%)	8/15 (53%)
Much more than usual		1/9 (11%)	1/15 (7%)
How is your memory?			
No worse than usual	3/6 (50%)	2/9 (22%)	5/15 (33%)
worse than usual	3/6 (50%)	6/9 (67%)	9/15 (60%)
Much worse than usual		1/9 (11%)	1/15 (7%)
Visit = Visit 2			
Observation	6	9	15
Do you have problems with tiredness?			
No more than usual	1/5 (20%)	4/9 (44%)	5/14 (36%)
More than usual	3/5 (60%)	3/9 (33%)	6/14 (43%)
Much more than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)

Variable	Placebo	Active	Total
Do you need to rest more?			
Less than usual		1/9 (11%)	1/14 (7%)
No more than usual	2/5 (40%)	3/9 (33%)	5/14 (36%)
More than usual	2/5 (40%)	4/9 (44%)	6/14 (43%)
Much more than usual	1/5 (20%)	1/9 (11%)	2/14 (14%)
Missing	1 (17%)		1 (7%)
Do you feel sleepy or drowsy?			
No more than usual	3/5 (60%)	5/9 (56%)	8/14 (57%)
More than usual	2/5 (40%)	2/9 (22%)	4/14 (29%)
Much more than usual		2/9 (22%)	2/14 (14%)
Missing	1 (17%)		1 (7%)
Do you have problems starting things?			
Less than usual		1/9 (11%)	1/14 (7%)
No more than usual	2/5 (40%)	4/9 (44%)	6/14 (43%)
More than usual	2/5 (40%)	2/9 (22%)	4/14 (29%)
Much more than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
Do you lack energy?			
No more than usual	2/5 (40%)	5/9 (56%)	7/14 (50%)
More than usual	2/5 (40%)		2/14 (14%)
Much more than usual	1/5 (20%)	4/9 (44%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Do you have less strength in your muscles?			
Less than usual		1/9 (11%)	1/14 (7%)
No more than usual	4/5 (80%)	5/9 (56%)	9/14 (64%)
More than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
Much more than usual		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
Do you feel weak?			
No more than usual	4/5 (80%)	6/9 (67%)	10/14 (71%)
More than usual	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
Do you have difficulties concentrating?			
No more than usual	2/5 (40%)	4/9 (44%)	6/14 (43%)
More than usual	2/5 (40%)		2/14 (14%)
Much more than usual	1/5 (20%)	5/9 (56%)	6/14 (43%)
Missing	1 (17%)		1 (7%)
Do you make slips of the tongue when speaking?			
No more than usual	4/5 (80%)	3/9 (33%)	7/14 (50%)
More than usual	1/5 (20%)	6/9 (67%)	7/14 (50%)
Missing	1 (17%)		1 (7%)
Do you find it more difficult to find the right words?			
Less than usual		1/9 (11%)	1/14 (7%)
No more than usual	3/5 (60%)	1/9 (11%)	4/14 (29%)
More than usual	1/5 (20%)	4/9 (44%)	5/14 (36%)
Much more than usual	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
How is your memory?			
Better than usual		1/9 (11%)	1/14 (7%)
No worse than usual	3/5 (60%)	5/9 (56%)	8/14 (57%)
worse than usual	2/5 (40%)	2/9 (22%)	4/14 (29%)
Much worse than usual		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
Visit = Visit 3			
Observation	5	9	14
Do you have problems with tiredness?			
No more than usual	1/5 (20%)	4/9 (44%)	5/14 (36%)
More than usual	4/5 (80%)	3/9 (33%)	7/14 (50%)
Much more than usual		2/9 (22%)	2/14 (14%)

Variable	Placebo	Active	Total
Do you need to rest more?			
No more than usual	1/5 (20%)	5/9 (56%)	6/14 (43%)
More than usual	4/5 (80%)	2/9 (22%)	6/14 (43%)
Much more than usual		2/9 (22%)	2/14 (14%)
Do you feel sleepy or drowsy?			
No more than usual	2/5 (40%)	4/9 (44%)	6/14 (43%)
More than usual	3/5 (60%)	2/9 (22%)	5/14 (36%)
Much more than usual		3/9 (33%)	3/14 (21%)
Do you have problems starting things?			
No more than usual	3/5 (60%)	4/9 (44%)	7/14 (50%)
More than usual	2/5 (40%)	4/9 (44%)	6/14 (43%)
Much more than usual		1/9 (11%)	1/14 (7%)
Do you lack energy?			
Less than usual		1/9 (11%)	1/14 (7%)
No more than usual	2/5 (40%)	2/9 (22%)	4/14 (29%)
More than usual	3/5 (60%)	2/9 (22%)	5/14 (36%)
Much more than usual		4/9 (44%)	4/14 (29%)
Do you have less strength in your muscles?			
Less than usual		1/9 (11%)	1/14 (7%)
No more than usual	4/5 (80%)	6/9 (67%)	10/14 (71%)
More than usual	1/5 (20%)		1/14 (7%)
Much more than usual		2/9 (22%)	2/14 (14%)
Do you feel weak?			
No more than usual	5/5 (100%)	6/9 (67%)	11/14 (79%)
More than usual		2/9 (22%)	2/14 (14%)
Much more than usual		1/9 (11%)	1/14 (7%)
Do you have difficulties concentrating?			
Less than usual		1/9 (11%)	1/14 (7%)
No more than usual	2/5 (40%)	1/9 (11%)	3/14 (21%)
More than usual	3/5 (60%)	3/9 (33%)	6/14 (43%)
Much more than usual		4/9 (44%)	4/14 (29%)
Do you make slips of the tongue when speaking?			
Less than usual		2/9 (22%)	2/14 (14%)
No more than usual	3/5 (60%)	2/9 (22%)	5/14 (36%)
More than usual	2/5 (40%)	5/9 (56%)	7/14 (50%)
Do you find it more difficult to find the right words?			
Less than usual		2/9 (22%)	2/14 (14%)
No more than usual	3/5 (60%)	2/9 (22%)	5/14 (36%)
More than usual	2/5 (40%)	4/9 (44%)	6/14 (43%)
Much more than usual		1/9 (11%)	1/14 (7%)
How is your memory?			
Better than usual	1/5 (20%)		1/14 (7%)
No worse than usual	2/5 (40%)	4/9 (44%)	6/14 (43%)
worse than usual	2/5 (40%)	5/9 (56%)	7/14 (50%)

Table 32QIDS-SR16
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
Falling asleep			
I never take longer than 30 minutes to fall asleep.	1/6 (17%)	2/9 (22%)	3/15 (20%)
I take at least 30 minutes to fall asleep, less than half the time (3 days or less out of the past 7 days)	3/6 (50%)	3/9 (33%)	6/15 (40%)
I take at least 30 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days)	1/6 (17%)	2/9 (22%)	3/15 (20%)
I take more than 60 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days).	1/6 (17%)	2/9 (22%)	3/15 (20%)
Sleep during the night			
I do not wake up at night		3/9 (33%)	3/15 (20%)
I have restless nights, sleeping lightly and wake up for a few brief periods each night	1/6 (17%)	2/9 (22%)	3/15 (20%)
I wake up at least one or more time a night, but I go back to sleep easily	3/6 (50%)	3/9 (33%)	6/15 (40%)
I wake up more than once a night and stay awake for 20 minutes or more, more than half the time (4 days or more out of the last 7 days)	2/6 (33%)	1/9 (11%)	3/15 (20%)
Waking up too early			
Most of the time, I wake up no more than 30 before I need to get up	3/6 (50%)	3/9 (33%)	6/15 (40%)
More than half the time (4 days or more out of the past 7 days), I woke up more than 30 minutes before my scheduled time	2/6 (33%)	3/9 (33%)	5/15 (33%)
I almost always wake up at least one hour or so before I need to, but I go back to sleep eventually	1/6 (17%)		1/15 (7%)
I wake up at least one hour before I need to, and cannot go back to sleep 4 days or more out of the last 7 days		3/9 (33%)	3/15 (20%)
Sleeping too much			
I sleep no longer than 7-8 hours/night, without napping during the day	3/6 (50%)	4/9 (44%)	7/15 (47%)
I sleep no longer than 10 hours in a 24-hour period including naps	2/6 (33%)	1/9 (11%)	3/15 (20%)
I sleep no longer than 12 hours in a 24-hour period including naps	1/6 (17%)	4/9 (44%)	5/15 (33%)
Feeling sad			
I do not feel sad.		1/9 (11%)	1/15 (7%)
I feel sad less than half the time (3 days or less out of the last 7 days)	2/6 (33%)	1/9 (11%)	3/15 (20%)
I feel sad more than half the time (4 days or more out of the last 7 days)	3/6 (50%)	2/9 (22%)	5/15 (33%)
I almost always feel sad	1/6 (17%)	5/9 (56%)	6/15 (40%)
Decreased appetite			
There is no change in my usual appetite	4/6 (67%)	3/7 (43%)	7/13 (54%)
I eat much less than usual and only with personal effort	2/6 (33%)	3/7 (43%)	5/13 (38%)
I rarely eat within a 24-hour period, and only with extreme personal effort or when others persuade me to eat		1/7 (14%)	1/13 (8%)
Missing		2 (22%)	2 (13%)
Increased appetite			
There is no change from my usual appetite	3/6 (50%)	4/8 (50%)	7/14 (50%)

Variable	Placebo	Active	Total
I feel a need to eat more frequently than usual	1/6 (17%)		1/14 (7%)
I regularly eat more often and/or greater amounts of food than usual	2/6 (33%)	3/8 (38%)	5/14 (36%)
I feel driven to overeat both at mealtime and between meals		1/8 (13%)	1/14 (7%)
Missing		1 (11%)	1 (7%)
Decreased weight (within the last two weeks)			
I have not had a change in my weight	6/6 (100%)	5/7 (71%)	11/13 (85%)
I feel as if I have had a slight weight loss		1/7 (14%)	1/13 (8%)
I have lost 2 pounds/1kg or more		1/7 (14%)	1/13 (8%)
Missing		2 (22%)	2 (13%)
Increased weight (within the last 2 weeks)			
I have not had a change in my weight	2/6 (33%)	4/8 (50%)	6/14 (43%)
I feel as if ive had a slight weight gain	1/6 (17%)	1/8 (13%)	2/14 (14%)
Ive gained 2 pounds/1kg or more	3/6 (50%)	2/8 (25%)	5/14 (36%)
Ive gained 5 pounds/2kg or more		1/8 (13%)	1/14 (7%)
Missing		1 (11%)	1 (7%)
Concentration/decision-making			
There is no change in my usual capacity to concentrate or make decisions.	1/6 (17%)		1/14 (7%)
I occasionally feel indecisive or find that my ettention wanders.	3/6 (50%)	2/8 (25%)	5/14 (36%)
Most of the time, I struggle to focus my attention or to make decisions	2/6 (33%)	4/8 (50%)	6/14 (43%)
I cannot concentrate well enough to read or cannot make even minor decisions.		2/8 (25%)	2/14 (14%)
Missing		1 (11%)	1 (7%)
View of myself			
I see myself as equally worthwhile and deserving as other people	1/6 (17%)		1/14 (7%)
I am more self-blaming than usual	3/6 (50%)	2/8 (25%)	5/14 (36%)
I largely believe that I cause problems for others		2/8 (25%)	2/14 (14%)
I think almost constantly about major and minor defects in myself	2/6 (33%)	4/8 (50%)	6/14 (43%)
Missing		1 (11%)	1 (7%)
Thoughts of death or suicide			
I do not think of suicide or death	4/6 (67%)	3/8 (38%)	7/14 (50%)
I feel that life is empty or wonder if it is worth living	2/6 (33%)	4/8 (50%)	6/14 (43%)
I have thought of suicide or death several times over the last seven days for several minutes		1/8 (13%)	1/14 (7%)
Missing		1 (11%)	1 (7%)
General interest			
There is no change from usual in how interested I was in other people or activities	1/6 (17%)	1/8 (13%)	2/14 (14%)
I notice that I am less interested in people or activities	1/6 (17%)		1/14 (7%)

Variable	Placebo	Active	Total
I find I have interest in only one or two of my formerly pursued activities	1/6 (17%)	3/8 (38%)	4/14 (29%)
I have very little interest in formerly pursued activities	3/6 (50%)	4/8 (50%)	7/14 (50%)
Missing		1 (11%)	1 (7%)
Energy level			
There is no change in my usual level of energy	1/6 (17%)	1/8 (13%)	2/14 (14%)
I get tired more easily than usual	2/6 (33%)	1/8 (13%)	3/14 (21%)
I have to make a big effort to start or finish my usual activities (for example, shopping, homework, cooking or going to work)	3/6 (50%)	6/8 (75%)	9/14 (64%)
Missing		1 (11%)	1 (7%)
Feeling slowed down			
I think, speak, and move at my usual rate of speed	4/6 (67%)	2/8 (25%)	6/14 (43%)
I find that my thinking is slower or my voice sounds dull or flat	2/6 (33%)	3/8 (38%)	5/14 (36%)
It takes me several seconds to respond to most questions and I am sure my thinking is slower		2/8 (25%)	2/14 (14%)
I am often unable to respond to questions without extreme effort		1/8 (13%)	1/14 (7%)
Missing		1 (11%)	1 (7%)
Feeling restless (agitated, not relaxed, fidgety)			
I do not feel restless	3/6 (50%)		3/14 (21%)
I am often fidgety, wringing my hand, or need to shift how I am sitting	3/6 (50%)	3/8 (38%)	6/14 (43%)
I have impulses to move about and am quite restless		4/8 (50%)	4/14 (29%)
At times, I am unable to stay seated and need to pace around		1/8 (13%)	1/14 (7%)
Missing		1 (11%)	1 (7%)
Visit = Visit 2			
Observation	6	9	15
Falling asleep			
I never take longer than 30 minutes to fall asleep.	3/5 (60%)	4/9 (44%)	7/14 (50%)
I take at least 30 minutes to fall asleep, less than half the time (3 days or less out of the past 7 days)		2/9 (22%)	2/14 (14%)
I take at least 30 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days)	1/5 (20%)	2/9 (22%)	3/14 (21%)
I take more than 60 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days).	1/5 (20%)	1/9 (11%)	2/14 (14%)
Missing	1 (17%)		1 (7%)
Sleep during the night			
I do not wake up at night		1/9 (11%)	1/14 (7%)
I have restless nights, sleeping lightly and wake up for a few brief periods each night		2/9 (22%)	2/14 (14%)
I wake up at least one or more time a night, but I go back to sleep easily	3/5 (60%)	6/9 (67%)	9/14 (64%)
I wake up more than once a night and stay awake for 20 minutes or more, more than half the time (4 days or more out of the last 7 days)	2/5 (40%)		2/14 (14%)
Missing	1 (17%)		1 (7%)
Waking up too early			
Most of the time, I wake up no more than 30 before I need to get up	3/5 (60%)	4/9 (44%)	7/14 (50%)

Variable	Placebo	Active	Total
More than half the time (4 days or more out of the past 7 days), I woke up more than 30 minutes before my scheduled time	1/5 (20%)	2/9 (22%)	3/14 (21%)
I almost always wake up at least one hour or so before I need to, but I go back to sleep eventually		1/9 (11%)	1/14 (7%)
I wake up at least one hour before I need to, and cannot go back to sleep 4 days or more out of the last 7 days	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
Sleeping too much			
I sleep no longer than 7-8 hours/night, without napping during the day	2/5 (40%)	5/9 (56%)	7/14 (50%)
I sleep no longer than 10 hours in a 24-hour period including naps	3/5 (60%)	3/9 (33%)	6/14 (43%)
I sleep no longer than 12 hours in a 24-hour period including naps		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
Feeling sad			
I do not feel sad.	1/5 (20%)		1/14 (7%)
I feel sad less than half the time (3 days or less out of the last 7 days)	2/5 (40%)	3/9 (33%)	5/14 (36%)
I feel sad more than half the time (4 days or more out of the last 7 days)	1/5 (20%)	4/9 (44%)	5/14 (36%)
I almost always feel sad	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
Decreased appetite			
There is no change in my usual appetite	4/5 (80%)	4/8 (50%)	8/13 (62%)
I eat rather less often or less amounts of food than usual.	1/5 (20%)	2/8 (25%)	3/13 (23%)
I eat much less than usual and only with personal effort		2/8 (25%)	2/13 (15%)
Missing	1 (17%)	1 (11%)	2 (13%)
Increased appetite			
There is no change from my usual appetite	3/5 (60%)	5/9 (56%)	8/14 (57%)
I feel a need to eat more frequently than usual		1/9 (11%)	1/14 (7%)
I regularly eat more often and/or greater amounts of food than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
I feel driven to overeat both at mealtime and between meals	1/5 (20%)	1/9 (11%)	2/14 (14%)
Missing	1 (17%)		1 (7%)
Decreased weight (within the last two weeks)			
I have not had a change in my weight	5/5 (100%)	8/8 (100%)	13/13 (100%)
Missing	1 (17%)	1 (11%)	2 (13%)
Increased weight (within the last 2 weeks)			
I have not had a change in my weight	2/5 (40%)	4/9 (44%)	6/14 (43%)
I feel as if ive had a slight weight gain	1/5 (20%)	2/9 (22%)	3/14 (21%)
Ive gained 2 pounds/1kg or more	2/5 (40%)	3/9 (33%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Concentration/decision-making			
There is no change in my usual capacity to concentrate or make decisions.	2/5 (40%)	1/9 (11%)	3/14 (21%)

Variable	Placebo	Active	Total
I occasionally feel indecisive or find that my attention wanders.	1/5 (20%)	2/9 (22%)	3/14 (21%)
Most of the time, I struggle to focus my attention or to make decisions	2/5 (40%)	6/9 (67%)	8/14 (57%)
Missing	1 (17%)		1 (7%)
View of myself			
I see myself as equally worthwhile and deserving as other people	2/5 (40%)	2/9 (22%)	4/14 (29%)
I am more self-blaming than usual	1/5 (20%)	1/9 (11%)	2/14 (14%)
I largely believe that I cause problems for others		1/9 (11%)	1/14 (7%)
I think almost constantly about major and minor defects in myself	2/5 (40%)	5/9 (56%)	7/14 (50%)
Missing	1 (17%)		1 (7%)
Thoughts of death or suicide			
I do not think of suicide or death	4/5 (80%)	5/9 (56%)	9/14 (64%)
I feel that life is empty or wonder if it is worth living		3/9 (33%)	3/14 (21%)
I have thought of suicide or death several times over the last seven days for several minutes	1/5 (20%)	1/9 (11%)	2/14 (14%)
Missing	1 (17%)		1 (7%)
General interest			
There is no change from usual in how interested I was in other people or activities	2/5 (40%)	2/9 (22%)	4/14 (29%)
I notice that I am less interested in people or activities	1/5 (20%)	3/9 (33%)	4/14 (29%)
I find I have interest in only one or two of my formerly pursued activities		1/9 (11%)	1/14 (7%)
I have very little interest in formerly pursued activities	2/5 (40%)	3/9 (33%)	5/14 (36%)
Missing	1 (17%)		1 (7%)
Energy level			
There is no change in my usual level of energy	1/5 (20%)	4/9 (44%)	5/14 (36%)
I get tired more easily than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
I have to make a big effort to start or finish my usual activities (for example, shopping, homework, cooking or going to work)	2/5 (40%)	1/9 (11%)	3/14 (21%)
I really cannot carry out most of my usual daily activities because I just didn't have the energy	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
Feeling slowed down			
I think, speak, and move at my usual rate of speed	3/5 (60%)	4/9 (44%)	7/14 (50%)
I find that my thinking is slower or my voice sounds dull or flat	2/5 (40%)	4/9 (44%)	6/14 (43%)
It takes me several seconds to respond to most questions and I am sure my thinking is slower		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
Feeling restless (agitated, not relaxed, fidgety)			
I do not feel restless	2/5 (40%)	3/9 (33%)	5/14 (36%)
I am often fidgety, wringing my hand, or need to shift how I am sitting	3/5 (60%)	1/9 (11%)	4/14 (29%)
I have impulses to move about and am quite restless		5/9 (56%)	5/14 (36%)
Missing	1 (17%)		1 (7%)

Variable	Placebo	Active	Total
Visit = Visit 3			
Observation	5	9	14
Falling asleep			
I never take longer than 30 minutes to fall asleep.	3/5 (60%)	5/9 (56%)	8/14 (57%)
I take at least 30 minutes to fall asleep, less than half the time (3 days or less out of the past 7 days)		2/9 (22%)	2/14 (14%)
I take at least 30 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days)	1/5 (20%)	1/9 (11%)	2/14 (14%)
I take more than 60 minutes to fall asleep, more than half the time (4 days or more out of the past 7 days).	1/5 (20%)	1/9 (11%)	2/14 (14%)
Sleep during the night			
I do not wake up at night		2/9 (22%)	2/14 (14%)
I have restless nights, sleeping lightly and wake up for a few brief periods each night	1/5 (20%)	3/9 (33%)	4/14 (29%)
I wake up at least one or more time a night, but I go back to sleep easily	4/5 (80%)	3/9 (33%)	7/14 (50%)
I wake up more than once a night and stay awake for 20 minutes or more, more than half the time (4 days or more out of the last 7 days)		1/9 (11%)	1/14 (7%)
Waking up too early			
Most of the time, I wake up no more than 30 before I need to get up	4/5 (80%)	5/9 (56%)	9/14 (64%)
More than half the time (4 days or more out of the past 7 days), I woke up more than 30 minutes before my scheduled time	1/5 (20%)	3/9 (33%)	4/14 (29%)
I wake up at least one hour before I need to, and cannot go back to sleep 4 days or more out of the last 7 days		1/9 (11%)	1/14 (7%)
Sleeping too much			
I sleep no longer than 7-8 hours/night, without napping during the day	2/5 (40%)	4/9 (44%)	6/14 (43%)
I sleep no longer than 10 hours in a 24-hour period including naps	3/5 (60%)	4/9 (44%)	7/14 (50%)
I sleep no longer than 12 hours in a 24-hour period including naps		1/9 (11%)	1/14 (7%)
Feeling sad			
I do not feel sad.		1/9 (11%)	1/14 (7%)
I feel sad less than half the time (3 days or less out of the last 7 days)	3/5 (60%)	4/9 (44%)	7/14 (50%)
I feel sad more than half the time (4 days or more out of the last 7 days)	2/5 (40%)	1/9 (11%)	3/14 (21%)
I almost always feel sad		3/9 (33%)	3/14 (21%)
Decreased appetite			
There is no change in my usual appetite	5/5 (100%)	6/9 (67%)	11/14 (79%)
I eat rather less often or less amounts of food than usual.		2/9 (22%)	2/14 (14%)
I eat much less than usual and only with personal effort		1/9 (11%)	1/14 (7%)
Increased appetite			
There is no change from my usual appetite	3/5 (60%)	6/9 (67%)	9/14 (64%)
I feel a need to eat more frequently than usual	1/5 (20%)		1/14 (7%)
I regularly eat more often and/or greater amounts of food than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)

Variable	Placebo	Active	Total
I feel driven to overeat both at mealtime and between meals		1/9 (11%)	1/14 (7%)
Decreased weight (within the last two weeks)			
I have not had a change in my weight	5/5 (100%)	9/9 (100%)	14/14 (100%)
Increased weight (within the last 2 weeks)			
I have not had a change in my weight	2/5 (40%)	6/9 (67%)	8/14 (57%)
I feel as if ive had a slight weight gain	1/5 (20%)		1/14 (7%)
Ive gained 2 pounds/1kg or more	1/5 (20%)	2/9 (22%)	3/14 (21%)
Ive gained 5 pounds/2kg or more	1/5 (20%)	1/9 (11%)	2/14 (14%)
Concentration/decision-making			
There is no change in my usual capacity to concentrate or make decisions.	2/5 (40%)	1/9 (11%)	3/14 (21%)
I occasionally feel indecisive or find that my ettention wanders.	2/5 (40%)	3/9 (33%)	5/14 (36%)
Most of the time, I struggle to focus my attention or to make decisions	1/5 (20%)	5/9 (56%)	6/14 (43%)
View of myself			
I see myself as equally worthwhile and deserving as other people	3/5 (60%)	1/9 (11%)	4/14 (29%)
I am more self-blaming than usual	1/5 (20%)	3/9 (33%)	4/14 (29%)
I think almost constantly about major and minor defects in myself	1/5 (20%)	5/9 (56%)	6/14 (43%)
Thoughts of death or suicide			
I do not think of suicide or death	4/5 (80%)	5/9 (56%)	9/14 (64%)
I feel that life is empty or wonder if it is worth living	1/5 (20%)	3/9 (33%)	4/14 (29%)
I have thought of suicide or death several times over the last seven days for several minutes		1/9 (11%)	1/14 (7%)
General interest			
There is no change from usual in how interested I was in other people or activities	2/5 (40%)	1/9 (11%)	3/14 (21%)
I notice that I am less interested in people or activities	1/5 (20%)	2/9 (22%)	3/14 (21%)
I find I have interest in only one or two of my formerly pursued activities	1/5 (20%)	1/9 (11%)	2/14 (14%)
I have very little interest in formerly pursued activities	1/5 (20%)	5/9 (56%)	6/14 (43%)
Energy level			
There is no change in my usual level of energy	1/5 (20%)	1/9 (11%)	2/14 (14%)
I get tired more easily than usual	1/5 (20%)	3/9 (33%)	4/14 (29%)
I have to make a big effort to start or finish my usual activities (for example, shopping, homework, cooking or going to work)	3/5 (60%)	4/9 (44%)	7/14 (50%)
I really cannot carry out most of my usual daily activities because I just didn't have the energy		1/9 (11%)	1/14 (7%)
Feeling slowed down			
I think, speak, and move at my usual rate of speed	4/5 (80%)	2/9 (22%)	6/14 (43%)
I find that my thinking is slower or my voice sounds dull or flat	1/5 (20%)	2/9 (22%)	3/14 (21%)

Variable	Placebo	Active	Total
It takes me several seconds to respond to most questions and I am sure my thinking is slower		5/9 (56%)	5/14 (36%)
Feeling restless (agitated, not relaxed, fidgety)			
I do not feel restless	3/5 (60%)	3/9 (33%)	6/14 (43%)
I am often fidgety, wringing my hand, or need to shift how I am sitting	2/5 (40%)	3/9 (33%)	5/14 (36%)
I have impulses to move about and am quite restless		2/9 (22%)	2/14 (14%)
At times, I am unable to stay seated and need to pace around		1/9 (11%)	1/14 (7%)

Table 33 Snaith-Hamilton Pleasure Scale (SHAPS)
Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
I would enjoy my favourite television or radio p			
Agree	2/6 (33%)	4/9 (44%)	6/15 (40%)
Disagree	3/6 (50%)	5/9 (56%)	8/15 (53%)
Definitely disagree	1/6 (17%)		1/15 (7%)
I would enjoy being with family or close friends			
Definitely agree	1/6 (17%)	3/9 (33%)	4/15 (27%)
Agree	2/6 (33%)	3/9 (33%)	5/15 (33%)
Disagree	3/6 (50%)	2/9 (22%)	5/15 (33%)
Definitely disagree		1/9 (11%)	1/15 (7%)
I would find pleasure in my hobbies and pastimes			
Agree		2/9 (22%)	2/15 (13%)
Disagree	4/6 (67%)	3/9 (33%)	7/15 (47%)
Definitely disagree	2/6 (33%)	4/9 (44%)	6/15 (40%)
I would be able to enjoy my favourite meal			
Definitely agree		2/9 (22%)	2/15 (13%)
Agree	1/6 (17%)	3/9 (33%)	4/15 (27%)
Disagree	3/6 (50%)	2/9 (22%)	5/15 (33%)
Definitely disagree	2/6 (33%)	2/9 (22%)	4/15 (27%)
I would enjoy a warm bath or refreshing shower			
Definitely agree	1/6 (17%)	3/9 (33%)	4/15 (27%)
Agree	4/6 (67%)	3/9 (33%)	7/15 (47%)
Disagree	1/6 (17%)	3/9 (33%)	4/15 (27%)
6. I would find pleasure in the scent of flowers			
Definitely agree	3/6 (50%)	2/9 (22%)	5/15 (33%)
Agree	2/6 (33%)	6/9 (67%)	8/15 (53%)
Disagree		1/9 (11%)	1/15 (7%)
Definitely disagree	1/6 (17%)		1/15 (7%)
I would enjoy seeing other peoples smiling faces			
Definitely agree		2/9 (22%)	2/15 (13%)
Agree	5/6 (83%)	4/9 (44%)	9/15 (60%)
Disagree		3/9 (33%)	3/15 (20%)
Definitely disagree	1/6 (17%)		1/15 (7%)
I would enjoy looking smart when I have made an ef			
Definitely agree		1/9 (11%)	1/15 (7%)
Agree	3/6 (50%)	2/9 (22%)	5/15 (33%)
Disagree	1/6 (17%)	5/9 (56%)	6/15 (40%)
Definitely disagree	2/6 (33%)	1/9 (11%)	3/15 (20%)
I would enjoy reading a book, magazine or newspaper			
Agree	3/6 (50%)	1/9 (11%)	4/15 (27%)
Disagree	2/6 (33%)	5/9 (56%)	7/15 (47%)
Definitely disagree	1/6 (17%)	3/9 (33%)	4/15 (27%)
I would enjoy a cup of tea or coffee or my favouri			
Definitely agree		3/9 (33%)	3/15 (20%)
Agree	5/6 (83%)	4/9 (44%)	9/15 (60%)
Disagree	1/6 (17%)	1/9 (11%)	2/15 (13%)
Definitely disagree		1/9 (11%)	1/15 (7%)
I would find pleasure in small things, e.g. bright			
Agree	4/6 (67%)	3/9 (33%)	7/15 (47%)
Disagree	1/6 (17%)	5/9 (56%)	6/15 (40%)
Definitely disagree	1/6 (17%)	1/9 (11%)	2/15 (13%)
I would be able to enjoy a beautiful landscape or			
Definitely agree	1/6 (17%)	1/9 (11%)	2/15 (13%)
Agree	4/6 (67%)	6/9 (67%)	10/15 (67%)
Disagree		2/9 (22%)	2/15 (13%)
Definitely disagree	1/6 (17%)		1/15 (7%)

Variable	Placebo	Active	Total
I would get pleasure from helping others			
Definitely agree		3/9 (33%)	3/14 (21%)
Agree	4/5 (80%)	3/9 (33%)	7/14 (50%)
Disagree	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
I would feel pleasure when I receive praise from o			
Definitely agree		3/9 (33%)	3/14 (21%)
Agree	3/5 (60%)	2/9 (22%)	5/14 (36%)
Disagree	1/5 (20%)	4/9 (44%)	5/14 (36%)
Definitely disagree	1/5 (20%)		1/14 (7%)
Missing	1 (17%)		1 (7%)
Visit = Visit 2			
Observation	6	9	15
I would enjoy my favourite television or radio p			
Agree	1/5 (20%)	6/9 (67%)	7/14 (50%)
Disagree	4/5 (80%)	3/9 (33%)	7/14 (50%)
Missing	1 (17%)		1 (7%)
I would enjoy being with family or close friends			
Definitely agree		2/9 (22%)	2/14 (14%)
Agree	2/5 (40%)	4/9 (44%)	6/14 (43%)
Disagree	3/5 (60%)	2/9 (22%)	5/14 (36%)
Definitely disagree		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
I would find pleasure in my hobbies and pastimes			
Agree		4/9 (44%)	4/14 (29%)
Disagree	4/5 (80%)	3/9 (33%)	7/14 (50%)
Definitely disagree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
I would be able to enjoy my favourite meal			
Definitely agree		4/9 (44%)	4/14 (29%)
Agree	3/5 (60%)	1/9 (11%)	4/14 (29%)
Disagree	2/5 (40%)	1/9 (11%)	3/14 (21%)
Definitely disagree		3/9 (33%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
I would enjoy a warm bath or refreshing shower			
Definitely agree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Agree	3/5 (60%)	4/9 (44%)	7/14 (50%)
Disagree	1/5 (20%)	3/9 (33%)	4/14 (29%)
Missing	1 (17%)		1 (7%)
6. I would find pleasure in the scent of flowers			
Definitely agree	2/5 (40%)	2/9 (22%)	4/14 (29%)
Agree	2/5 (40%)	4/9 (44%)	6/14 (43%)
Disagree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Definitely disagree		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
I would enjoy seeing other peoples smiling faces			
Definitely agree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Agree	3/5 (60%)	6/9 (67%)	9/14 (64%)
Disagree		1/9 (11%)	1/14 (7%)
Definitely disagree	1/5 (20%)		1/14 (7%)
Missing	1 (17%)		1 (7%)
I would enjoy looking smart when I have made an ef			
Definitely agree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Agree	2/5 (40%)	3/9 (33%)	5/14 (36%)
Disagree	1/5 (20%)	4/9 (44%)	5/14 (36%)
Definitely disagree	1/5 (20%)		1/14 (7%)
Missing	1 (17%)		1 (7%)
I would enjoy reading a book, magazine or newspape			
Agree	3/5 (60%)	2/9 (22%)	5/14 (36%)

Variable	Placebo	Active	Total
Disagree	2/5 (40%)	4/9 (44%)	6/14 (43%)
Definitely disagree		3/9 (33%)	3/14 (21%)
Missing	1 (17%)		1 (7%)
I would enjoy a cup of tea or coffee or my favourite			
Definitely agree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Agree	3/5 (60%)	4/9 (44%)	7/14 (50%)
Disagree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Definitely disagree		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
I would find pleasure in small things, e.g. bright			
Definitely agree	2/5 (40%)	1/9 (11%)	3/14 (21%)
Agree	2/5 (40%)	5/9 (56%)	7/14 (50%)
Disagree	1/5 (20%)	1/9 (11%)	2/14 (14%)
Definitely disagree		2/9 (22%)	2/14 (14%)
Missing	1 (17%)		1 (7%)
I would be able to enjoy a beautiful landscape or			
Definitely agree	2/5 (40%)	1/9 (11%)	3/14 (21%)
Agree	2/5 (40%)	5/9 (56%)	7/14 (50%)
Disagree		3/9 (33%)	3/14 (21%)
Definitely disagree	1/5 (20%)		1/14 (7%)
Missing	1 (17%)		1 (7%)
I would get pleasure from helping others			
Definitely agree	2/5 (40%)	3/9 (33%)	5/14 (36%)
Agree	3/5 (60%)	5/9 (56%)	8/14 (57%)
Disagree		1/9 (11%)	1/14 (7%)
Missing	1 (17%)		1 (7%)
I would feel pleasure when I receive praise from o			
Definitely agree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Agree	1/5 (20%)	3/9 (33%)	4/14 (29%)
Disagree	2/5 (40%)	4/9 (44%)	6/14 (43%)
Definitely disagree	1/5 (20%)		1/14 (7%)
Missing	1 (17%)		1 (7%)
Visit = Visit 3			
Observation	5	9	14
I would enjoy my favourite television or radio p			
Definitely agree	1/5 (20%)		1/14 (7%)
Agree	2/5 (40%)	4/9 (44%)	6/14 (43%)
Disagree	2/5 (40%)	2/9 (22%)	4/14 (29%)
Definitely disagree		3/9 (33%)	3/14 (21%)
I would enjoy being with family or close friends			
Definitely agree	1/5 (20%)	1/9 (11%)	2/14 (14%)
Agree	2/5 (40%)	4/9 (44%)	6/14 (43%)
Disagree	2/5 (40%)	3/9 (33%)	5/14 (36%)
Definitely disagree		1/9 (11%)	1/14 (7%)
I would find pleasure in my hobbies and pastimes			
Agree	4/5 (80%)	3/8 (38%)	7/13 (54%)
Disagree	1/5 (20%)	3/8 (38%)	4/13 (31%)
Definitely disagree		2/8 (25%)	2/13 (15%)
Missing		1 (11%)	1 (7%)
I would be able to enjoy my favourite meal			
Definitely agree		2/9 (22%)	2/14 (14%)
Agree	5/5 (100%)	1/9 (11%)	6/14 (43%)
Disagree		4/9 (44%)	4/14 (29%)
Definitely disagree		2/9 (22%)	2/14 (14%)
I would enjoy a warm bath or refreshing shower			
Definitely agree	1/5 (20%)		1/14 (7%)
Agree	4/5 (80%)	7/9 (78%)	11/14 (79%)
Disagree		2/9 (22%)	2/14 (14%)
6. I would find pleasure in the scent of flowers			

Variable	Placebo	Active	Total
Definitely agree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Agree	4/5 (80%)	3/9 (33%)	7/14 (50%)
Disagree		3/9 (33%)	3/14 (21%)
Definitely disagree		1/9 (11%)	1/14 (7%)
I would enjoy seeing other peoples smiling faces			
Definitely agree		1/9 (11%)	1/14 (7%)
Agree	4/5 (80%)	4/9 (44%)	8/14 (57%)
Disagree	1/5 (20%)	3/9 (33%)	4/14 (29%)
Definitely disagree		1/9 (11%)	1/14 (7%)
I would enjoy looking smart when I have made an ef			
Definitely agree		1/9 (11%)	1/14 (7%)
Agree	4/5 (80%)	3/9 (33%)	7/14 (50%)
Disagree	1/5 (20%)	3/9 (33%)	4/14 (29%)
Definitely disagree		2/9 (22%)	2/14 (14%)
I would enjoy reading a book, magazine or newspaper			
Definitely agree	1/5 (20%)		1/14 (7%)
Agree	3/5 (60%)	3/9 (33%)	6/14 (43%)
Disagree	1/5 (20%)	3/9 (33%)	4/14 (29%)
Definitely disagree		3/9 (33%)	3/14 (21%)
I would enjoy a cup of tea or coffee or my favouri			
Definitely agree	1/5 (20%)	1/9 (11%)	2/14 (14%)
Agree	4/5 (80%)	4/9 (44%)	8/14 (57%)
Disagree		3/9 (33%)	3/14 (21%)
Definitely disagree		1/9 (11%)	1/14 (7%)
I would find pleasure in small things, e.g. bright			
Definitely agree	2/5 (40%)		2/14 (14%)
Agree	2/5 (40%)	4/9 (44%)	6/14 (43%)
Disagree	1/5 (20%)	4/9 (44%)	5/14 (36%)
Definitely disagree		1/9 (11%)	1/14 (7%)
I would be able to enjoy a beautiful landscape or			
Definitely agree	1/5 (20%)	1/9 (11%)	2/14 (14%)
Agree	3/5 (60%)	6/9 (67%)	9/14 (64%)
Disagree	1/5 (20%)	1/9 (11%)	2/14 (14%)
Definitely disagree		1/9 (11%)	1/14 (7%)
I would get pleasure from helping others			
Definitely agree	2/5 (40%)		2/14 (14%)
Agree	3/5 (60%)	7/9 (78%)	10/14 (71%)
Disagree		2/9 (22%)	2/14 (14%)
I would feel pleasure when I receive praise from o			
Definitely agree	1/5 (20%)	2/9 (22%)	3/14 (21%)
Agree	3/5 (60%)	2/9 (22%)	5/14 (36%)
Disagree	1/5 (20%)	4/9 (44%)	5/14 (36%)
Definitely disagree		1/9 (11%)	1/14 (7%)

Table 34 Beck Depression Inventory (BDI)
Visit 1 Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Visit 1			
Observation	6	9	15
BDI Question 1:			
I do not feel sad		1/9 (11%)	1/15 (7%)
I feel sad much of the time	3/6 (50%)	3/9 (33%)	6/15 (40%)
I'm sad all the time	3/6 (50%)	4/9 (44%)	7/15 (47%)
I'm so sad and unhappy that I can't stand it		1/9 (11%)	1/15 (7%)
BDI Question 2:			
I am not discouraged about my future	1/6 (17%)	1/9 (11%)	2/15 (13%)
I feel more discouraged about my future than I used to be.	4/6 (67%)	4/9 (44%)	8/15 (53%)
I do not expect things to work out for me		1/9 (11%)	1/15 (7%)
I feel my future is hopeless and will only get worse	1/6 (17%)	3/9 (33%)	4/15 (27%)
BDI Question 3:			
I do not feel like a failure	1/6 (17%)		1/15 (7%)
I feel I have failed more than I should have	1/6 (17%)	3/9 (33%)	4/15 (27%)
As I look back, I see a lot of failures	4/6 (67%)	4/9 (44%)	8/15 (53%)
I feel I am total failure as a person		2/9 (22%)	2/15 (13%)
BDI Question 4:			
I don't enjoy things as much as I used to	3/6 (50%)	2/9 (22%)	5/15 (33%)
I get very little pleasure from the things I used to enjoy	3/6 (50%)	5/9 (56%)	8/15 (53%)
I can't get any pleasure from the things I used to enjoy		2/9 (22%)	2/15 (13%)
BDI Question 5:			
I don't feel particularly guilty	1/6 (17%)		1/15 (7%)
I feel guilty over many things I have done or should have done	3/6 (50%)	1/9 (11%)	4/15 (27%)
I feel quite guilty most of the time	1/6 (17%)		1/15 (7%)
I feel guilty all of the time	1/6 (17%)	8/9 (89%)	9/15 (60%)
BDI Question 6:			
I don't feel I am being punished	6/6 (100%)	1/9 (11%)	7/15 (47%)
I feel I may be punished		3/9 (33%)	3/15 (20%)
I expect to be punished		3/9 (33%)	3/15 (20%)
I feel I am being punished		2/9 (22%)	2/15 (13%)
BDI Question 7:			
I feel the same about myself as ever	1/6 (17%)		1/15 (7%)
I have lose confidence in myself	3/6 (50%)	4/9 (44%)	7/15 (47%)
I am disappointed in myself	2/6 (33%)	1/9 (11%)	3/15 (20%)

Variable	Placebo	Active	Total
I dislike myself		4/9 (44%)	4/15 (27%)
BDI Question 8:			
I don't criticize or blame myself more than usual	1/6 (17%)		1/15 (7%)
I am more critical of myself than I used to be	1/6 (17%)	2/9 (22%)	3/15 (20%)
I criticize myself for all of my faults	4/6 (67%)	1/9 (11%)	5/15 (33%)
I blame myself for everything bad that happens		6/9 (67%)	6/15 (40%)
BDI Question 9:			
I don't have any thoughts of killing myself	4/6 (67%)	4/9 (44%)	8/15 (53%)
I have thoughts of killing myself, but I would not carry them out	1/6 (17%)	5/9 (56%)	6/15 (40%)
I would like to kill myself	1/6 (17%)		1/15 (7%)
BDI Question 10:			
I don't cry any more than I used to	2/6 (33%)	1/9 (11%)	3/15 (20%)
I cry more than I used to	3/6 (50%)	1/9 (11%)	4/15 (27%)
I cry over every little thing	1/6 (17%)	4/9 (44%)	5/15 (33%)
I feel like crying, but I can't		2/9 (22%)	2/15 (13%)
Missing		1/9 (11%)	1/15 (7%)
BDI Question 11:			
I am no more restless or wound up than usual	3/6 (50%)	2/9 (22%)	5/15 (33%)
I feel more restless or wound up than usual	2/6 (33%)	3/9 (33%)	5/15 (33%)
I am so restless or agitated that it's hard to stay still	1/6 (17%)	4/9 (44%)	5/15 (33%)
BDI Question 12:			
I have not lost interest in other people or activities	1/6 (17%)		1/15 (7%)
I am less interested in other people or things than before	3/6 (50%)	1/9 (11%)	4/15 (27%)
I have lost most of my interest in other people or things	1/6 (17%)	5/9 (56%)	6/15 (40%)
It's hard to get interested in anything	1/6 (17%)	3/9 (33%)	4/15 (27%)
BDI Question 13:			
I make decisions about as well as ever	1/6 (17%)		1/15 (7%)
I find it more difficult to make decisions than usual	3/6 (50%)	3/9 (33%)	6/15 (40%)
I have much greater difficulty in making decisions than I used to	2/6 (33%)	4/9 (44%)	6/15 (40%)
I have trouble making any decisions		2/9 (22%)	2/15 (13%)
BDI Question 14:			
I do not feel I am worthless	2/6 (33%)	2/9 (22%)	4/15 (27%)
I don't consider myself as worthwhile and useful as I used to	1/6 (17%)	3/9 (33%)	4/15 (27%)
I feel more worthless as compared to other people	2/6 (33%)	3/9 (33%)	5/15 (33%)
I feel utterly worthless	1/6 (17%)	1/9 (11%)	2/15 (13%)

Variable	Placebo	Active	Total
BDI Question 15:			
I have as much energy as ever	1/6 (17%)		1/15 (7%)
I have less energy than I used to have	2/6 (33%)	2/9 (22%)	4/15 (27%)
I don't have enough energy to do very much	2/6 (33%)	7/9 (78%)	9/15 (60%)
I don't have enough energy to do anything	1/6 (17%)		1/15 (7%)
BDI Question 16:			
I have not experienced any change in my sleeping pattern	1/6 (17%)		1/15 (7%)
I sleep somewhat more than usual	3/6 (50%)	1/9 (11%)	4/15 (27%)
I sleep somewhat less than usual	1/6 (17%)		1/15 (7%)
I sleep a lot more than usual		5/9 (56%)	5/15 (33%)
I sleep a lot less than usual		2/9 (22%)	2/15 (13%)
I wake up 1-2 hours early and can't get back to sleep	1/6 (17%)	1/9 (11%)	2/15 (13%)
BDI Question 17:			
I am no more irritable than usual	3/6 (50%)	3/9 (33%)	6/15 (40%)
I am more irritable than usual	3/6 (50%)	3/9 (33%)	6/15 (40%)
I am much more irritable than usual		1/9 (11%)	1/15 (7%)
I am irritable all the time		2/9 (22%)	2/15 (13%)
BDI Question 18:			
I have not experienced any change in my appetite	1/6 (17%)	1/9 (11%)	2/15 (13%)
My appetite is somewhat less than usual	1/6 (17%)		1/15 (7%)
My appetite is somewhat greater than usual	4/6 (67%)		4/15 (27%)
My appetite is much less than before		3/9 (33%)	3/15 (20%)
My appetite is much greater than usual		5/9 (56%)	5/15 (33%)
BDI Question 19:			
I can concentrate as well as ever	1/6 (17%)		1/15 (7%)
I can't concentrate as well as usual	2/6 (33%)	2/9 (22%)	4/15 (27%)
It's hard to keep my mind on anything for very long	3/6 (50%)	5/9 (56%)	8/15 (53%)
I find I can't concentrate on anything		2/9 (22%)	2/15 (13%)
BDI Question 20:			
I am no more tired or fatigued than usual	1/6 (17%)		1/15 (7%)
I get more tired or fatigued more easily than usual	3/6 (50%)	3/9 (33%)	6/15 (40%)
I am too tired or fatigued to do a lot of things I used to do	2/6 (33%)	2/9 (22%)	4/15 (27%)
I am too tired or fatigued to do most of the things I used to do		4/9 (44%)	4/15 (27%)
BDI Question 21:			
I have not noticed any recent change in my interest in sex	2/6 (33%)	2/9 (22%)	4/15 (27%)
I am less interested in sex than I used to be	2/6 (33%)	2/9 (22%)	4/15 (27%)

Variable	Placebo	Active	Total
I am much less interested in sex now	1/6 (17%)	2/9 (22%)	3/15 (20%)
I have lost interest in sex completely	1/6 (17%)	3/9 (33%)	4/15 (27%)

Table 35 Beck Depression Inventory (BDI)
Follow-up Population: Full (n = 15)

Variable	Placebo	Active	Total
Visit = Follow-up			
Observation	5	9	14
BDI Question 1:			
I do not feel sad	1/5 (20%)	1/9 (11%)	2/14 (14%)
I feel sad much of the time	4/5 (80%)	6/9 (67%)	10/14 (71%)
I'm sad all the time		2/9 (22%)	2/14 (14%)
BDI Question 2:			
I am not discouraged about my future	2/5 (40%)	4/9 (44%)	6/14 (43%)
I feel more discouraged about my future than I used to be.	1/5 (20%)	1/9 (11%)	2/14 (14%)
I do not expect things to work out for me	2/5 (40%)	4/9 (44%)	6/14 (43%)
BDI Question 3:			
I do not feel like a failure	2/5 (40%)	1/9 (11%)	3/14 (21%)
I feel I have failed more than I should have	1/5 (20%)	1/9 (11%)	2/14 (14%)
As I look back, I see a lot of failures	2/5 (40%)	5/9 (56%)	7/14 (50%)
I feel I am total failure as a person		2/9 (22%)	2/14 (14%)
BDI Question 4:			
I get as much pleasure as I ever did from the things I enjoy		1/9 (11%)	1/14 (7%)
I don't enjoy things as much as I used to	4/5 (80%)	3/9 (33%)	7/14 (50%)
I get very little pleasure from the things I used to enjoy	1/5 (20%)	3/9 (33%)	4/14 (29%)
I can't get any pleasure from the things I used to enjoy		2/9 (22%)	2/14 (14%)
BDI Question 5:			
I don't feel particularly guilty	1/5 (20%)		1/14 (7%)
I feel guilty over many things I have done or should have done	4/5 (80%)	3/9 (33%)	7/14 (50%)
I feel quite guilty most of the time		3/9 (33%)	3/14 (21%)
I feel guilty all of the time		3/9 (33%)	3/14 (21%)
BDI Question 6:			
I don't feel I am being punished	5/5 (100%)	2/9 (22%)	7/14 (50%)
I feel I may be punished		3/9 (33%)	3/14 (21%)
I expect to be punished		3/9 (33%)	3/14 (21%)
I feel I am being punished		1/9 (11%)	1/14 (7%)
BDI Question 7:			
I feel the same about myself as ever	1/5 (20%)	1/9 (11%)	2/14 (14%)
I have lose confidence in myself	1/5 (20%)	2/9 (22%)	3/14 (21%)

Variable	Placebo	Active	Total
I am disappointed in myself	3/5 (60%)	3/9 (33%)	6/14 (43%)
I dislike myself		3/9 (33%)	3/14 (21%)
BDI Question 8:			
I don't criticize or blame myself more than usual	1/5 (20%)	1/9 (11%)	2/14 (14%)
I am more critical of myself than I used to be	3/5 (60%)	2/9 (22%)	5/14 (36%)
I criticize myself for all of my faults	1/5 (20%)	3/9 (33%)	4/14 (29%)
I blame myself for everything bad that happens		3/9 (33%)	3/14 (21%)
BDI Question 9:			
I don't have any thoughts of killing myself	4/5 (80%)	6/9 (67%)	10/14 (71%)
I have thoughts of killing myself, but I would not carry them out	1/5 (20%)	3/9 (33%)	4/14 (29%)
BDI Question 10:			
I don't cry any more than I used to	3/5 (60%)	4/9 (44%)	7/14 (50%)
I cry more than I used to	1/5 (20%)	3/9 (33%)	1/14 (7%)
I cry over every little thing		3/9 (33%)	3/14 (21%)
I feel like crying, but I can't	1/5 (20%)	2/9 (22%)	3/14 (21%)
BDI Question 11:			
I am no more restless or wound up than usual	2/5 (40%)	2/9 (22%)	4/14 (29%)
I feel more restless or wound up than usual	3/5 (60%)	4/9 (44%)	7/14 (50%)
I am so restless or agitated that it's hard to stay still		2/9 (22%)	2/14 (14%)
I am so restless or agitated that I have to keep moving or doing something		1/9 (11%)	1/14 (7%)
BDI Question 12:			
I have not lost interest in other people or activities	1/5 (20%)	1/9 (11%)	2/14 (14%)
I am less interested in other people or things than before	3/5 (60%)	4/9 (44%)	7/14 (50%)
I have lost most of my interest in other people or things	1/5 (20%)	2/9 (22%)	3/14 (21%)
It's hard to get interested in anything		2/9 (22%)	2/14 (14%)
BDI Question 13:			
I make decisions about as well as ever	1/5 (20%)	1/9 (11%)	2/14 (14%)
I find it more difficult to make decisions than usual	3/5 (60%)	4/9 (44%)	7/14 (50%)
I have much greater difficulty in making decisions than I used to	1/5 (20%)	2/9 (22%)	3/14 (21%)
I have trouble making any decisions		2/9 (22%)	2/14 (14%)
BDI Question 14:			
I do not feel I am worthless	1/5 (20%)	1/9 (11%)	2/14 (14%)
I don't consider myself as worthwhile and useful as I used to	3/5 (60%)	2/9 (22%)	5/14 (36%)

Variable	Placebo	Active	Total
I feel more worthless as compared to other people	1/5 (20%)	5/9 (56%)	6/14 (43%)
I feel utterly worthless		1/9 (11%)	1/14 (7%)
BDI Question 15:			
I have as much energy as ever	1/5 (20%)	1/9 (11%)	2/14 (14%)
I have less energy than I used to have	1/5 (20%)	2/9 (22%)	3/14 (21%)
I don't have enough energy to do very much	3/5 (60%)	6/9 (67%)	9/14 (64%)
BDI Question 16:			
I have not experienced any change in my sleeping pattern	3/5 (60%)	4/9 (44%)	7/14 (50%)
I sleep somewhat more than usual	1/5 (20%)	1/9 (11%)	2/14 (14%)
I sleep somewhat less than usual	1/5 (20%)	1/9 (11%)	2/14 (14%)
I sleep a lot more than usual		3/9 (33%)	3/14 (21%)
BDI Question 17:			
I am no more irritable than usual	4/5 (80%)	3/9 (33%)	7/14 (50%)
I am more irritable than usual		4/9 (44%)	4/14 (29%)
I am much more irritable than usual	1/5 (20%)	1/9 (11%)	2/14 (14%)
I am irritable all the time		1/9 (11%)	1/14 (7%)
BDI Question 18:			
I have not experienced any change in my appetite	2/5 (40%)	3/9 (33%)	5/14 (36%)
My appetite is somewhat less than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
My appetite is somewhat greater than usual	1/5 (20%)	1/9 (11%)	2/14 (14%)
My appetite is much greater than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
I crave food all the time		1/9 (11%)	1/14 (7%)
BDI Question 19:			
I can concentrate as well as ever	1/5 (20%)	1/9 (11%)	2/14 (14%)
I can't concentrate as well as usual	2/5 (40%)	3/9 (33%)	5/14 (36%)
It's hard to keep my mind on anything for very long	2/5 (40%)	4/9 (44%)	6/14 (43%)
I find I can't concentrate on anything		1/9 (11%)	1/14 (7%)
BDI Question 20:			
I am no more tired or fatigued than usual	1/5 (20%)	2/9 (22%)	3/14 (21%)
I get more tired or fatigued more easily than usual	4/5 (80%)	1/9 (11%)	5/14 (36%)
I am too tired or fatigued to do a lot of things I used to do		5/9 (56%)	5/14 (36%)
I am too tired or fatigued to do most of the things I used to do		1/9 (11%)	1/14 (7%)
BDI Question 21:			

Variable	Placebo	Active	Total
I have not noticed any recent change in my interest in sex	2/5 (40%)	3/9 (33%)	5/14 (36%)
I am less interested in sex than I used to be	2/5 (40%)	1/9 (11%)	3/14 (21%)
I am much less interested in sex now	1/5 (20%)		1/14 (7%)
I have lost interest in sex completely		5/9 (56%)	5/14 (36%)

Section: Concomitant Medication
Table 36 Concomitant medications
Listing Population: Full (n = 15)

Participant ID	Group	Site	Concomitant Medication Name	Indication	Dose	Other dose	Units	Frequency	Other Frequency, please specify	Route	Other Route, please specify	Start Date	Pre Study	Ongoing ?	End date	Conmed used for treatment of AE/SAE?	AE no
10004	Active	N01	Vitamin D	Low vitamin D	1000		IU	Once daily		Oral			Ticked	Yes		No	
10004	Active	N01	Levothyroxine	Thyroid operation 1991	100		MCG	Once daily		Oral			Ticked	Yes		No	
10004	Active	N01	Paracetamol	Cold	1		g	Once daily		Oral		2019-10-14	Ticked	No	2019-10-25	No	
10004	Active	N01	Cold & Flu Relief Remedy	Cold				Once daily		Oral		2019-10-16	Ticked	No	2019-10-25	No	
10004	Active	N01	Paracetamol	Headache	1000		mg	As required		Oral		2019-12-13	Not Ticked	No	2019-12-13	Yes	2
10004	Active	N01	Eye Drops	Dry itchy eyes		drops		As required		Topical			Not Ticked			No	
10004	Active	N01	Paracetamol	Cold symptoms (muscle aches, fever, headache)	1000		mg	As required		Oral		2019-12-24	Not Ticked	No	2019-12-27	Yes	4
10004	Active	N01	Ibuprofen	Cold symptoms (muscle aches, fever, headache)	400		mg	As required		Oral		2019-12-24	Not Ticked	No	2019-12-25	Yes	4
10006	Placebo	N01	Depopduera	Contraception	150		mg	Other (please specify)	12 weeks	Other (please specify)	intramuscular		Ticked	Yes		No	
10006	Placebo	N01	Paracetamol	Headache	1		mg	As required		Oral			Ticked	No		No	
10019	Placebo	N01	Boots Multivitamin	Supporting diet		1 tablet		Once daily		Oral			Ticked	Yes		No	
10019	Placebo	N01	Kalms	Anxiety and sleep		not known		Twice daily		Oral			Ticked	No		No	
10019	Placebo	N01	Astrazenica Vaccine (Covid-19)	2nd dose of vaccine for Covid-19		1 injection		As required		Subcutaneous		2021-05-30	Ticked	No	2021-05-30	No	

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Participant ID	Group	Site	Concomitant Medication Name	Indication	Dose	Other dose	Units	Frequency	Other Frequency, please specify	Route	Other Route, please specify	Start Date	Pre Study	Ongoing ?	End date	Conmed used for treatment of AE/SAE?	AE no.
10019	Placebo	N01	Paracetamol	Aches from cutting the grass	1000		mg	Once daily		Oral		2021-06-14	Not Ticked	No	2021-06-14	Yes	1
10019	Placebo	N01	Paracetamol	Sore throat	1000		mg	Once daily		Oral		2021-07-08	Not Ticked	No	2021-07-10	Yes	2
10019	Placebo	N01	Paracetamol	Aching legs more than usual	1000		mg	Once daily		Oral		2021-07-17	Not Ticked	No	2021-07-20	Yes	3
10019	Placebo	N01	Paracetamol	General aches	1000		mg	As required		Oral		2021-08-02	Not Ticked	No	2021-08-02	No	
10036	Active	N01	Covid 19 booster	Covid 19				Once daily		Subcutaneous		2022-01-27	Ticked	No	2022-01-27	No	
10036	Active	N01	Paracetamol	Prn	500		mg	As required		Oral			Ticked	Yes		No	
10036	Active	N01	Ibuprofen	Prn	400		mg	As required		Oral			Ticked	Yes		No	
10036	Active	N01	Becothamethanol inhaler	Asthma	50		micrograms	As required		Other (please specify)	inhaled		Ticked	Yes		No	
10036	Active	N01	Co-codamol	Chest Pain	400	8mg x 2	mg	As required		Oral		2022-04-04	Not Ticked	No	2022-04-11	Yes	2
10036	Active	N01	Robitussin Mucus Cough medicine	Cold /cough	20		ml	As required		Oral		2022-04-07	Not Ticked	No	2022-04-07	Yes	1
10038	Placebo	N01	Paracetamol	Headaches	100		mg	As required		Oral		1995-01-01	Ticked	Yes		No	
10038	Placebo	N01	Ibuprofen	Headaches	400		mg	As required		Oral		2012-01-01	Ticked	Yes		No	
10038	Placebo	N01	Multivitamin with iron	To improve diet. some anaemia in childhood				Once daily		Oral		2012-01-01	Ticked	Yes		No	
10038	Placebo	N01	Becanase	To relieve nasal congestion snoring	100		mls	Twice daily		Other (please specify)	each nostril	2022-05-25	Not Ticked	Yes		No	

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Participant ID	Group	Site	Concomitant Medication Name	Indication	Dose	Other dose	Units	Frequency	Other Frequency, please specify	Route	Other Route, please specify	Start Date	Pre Study	Ongoing ?	End date	Conmed used for treatment of AE/SAE?	AE no.
30002	Active	N03	Vitamin D	Vitamin immune booster		300?	mg	Other (please specify)	couple of times a week	Oral		2020-11-24	Ticked	No	2021-06-07	No	
30002	Active	N03	Citalopram	Depression	10		mg	Once daily		Oral			Ticked	Yes		No	
30002	Active	N03	Senna laxative	Constipation		7.5	g	As required		Oral		2021-08-06	Not Ticked	No	2021-08-06	Yes	4
30002	Active	N03	Paracetamol	Headache and blocked nose	2500	2 x 500	mg	As required		Oral		2021-06-27	Not Ticked	No	2021-07-27	No	
30002	Active	N03	Ibuprofen	Unknown (reported in medication diary)	2		tablets (not exact)	Once daily		Oral		2021-07-01	Not Ticked	No	2021-07-01		
30006	Placebo	N03	Multivitamins	General health and wellbeing	1			Once daily		Oral		2000-06-15	Not Ticked	Yes		No	
30006	Placebo	N03	COVID-19 booster vaccine	COVID-19 IMMUNITY	1			Other (please specify)	One off	Intravenous		2020-11-25	Not Ticked	No	2021-11-26	No	
30011	Placebo	N03	Sumatriptan	Migraines	100		mg	As required		Oral			Ticked	Yes		No	
30011	Placebo	N03	Ibuprofen	Headaches	400		mg	As required		Oral			Ticked	Yes		No	
30011	Placebo	N03	Ibuprofen	Headaches	400		mg	As required		Oral		2022-02-20	Not Ticked	Yes		No	
30011	Placebo	N03	Ibuprofen	Headaches	200		mg	As required		Oral		2022-02-25	Not Ticked	No	2022-02-27	Yes	1
30011	Placebo	N03	Naratriptan	Migraines	3		mg	As required		Oral		2022-02-25	Not Ticked	No	2022-02-25	Yes	1
30011	Placebo	N03	Ibuprofen	Headaches	200		mg	As required		Oral		2022-03-04	Not Ticked	No	2022-03-25	Yes	2
30011	Placebo	N03	Ibuprofen	Headaches	200		mg	As required		Oral		2022-03-15	Not Ticked	No	2022-03-18	Yes	3
30011	Placebo	N03	Sumatriptan	Migraines	50		mg	Once daily		Oral		2022-04-13	Not Ticked	No	2022-04-13	Yes	6

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Participant ID	Group	Site	Concomitant Medication Name	Indication	Dose	Other dose	Units	Frequency	Other Frequency, please specify	Route	Other Route, please specify	Start Date	Pre Study	Ongoing ?	End date	Conmed used for treatment of AE/SAE?	AE no.
30011	Placebo	N03	Ibuprofen	Headache	200		mg	Twice daily		Oral		2022-04-19	Not Ticked	No	2022-04-19	Yes	6
30011	Placebo	N03	Ibuprofen	Headache	200		mg	Once daily		Oral		2022-04-20	Not Ticked	No	2022-04-20	Yes	6
30011	Placebo	N03	Ibuprofen	Mild headache	200		mg	Twice daily		Oral		2022-03-27	Not Ticked	No	2022-03-27	Yes	4
30011	Placebo	N03	Ibuprofen	Headache and Covid	200		mg	Twice daily		Oral		2022-04-09	Not Ticked	No	2022-04-09	Yes	5
30011	Placebo	N03	Ibuprofen	Headache and Covid	200		mg	Once daily		Oral		2022-04-13	Not Ticked	No	2022-04-13	Yes	5
30011	Placebo	N03	Ibuprofen	Covid symptoms sore throat	200		mg	Three times daily		Oral		2022-04-17	Not Ticked	No	2022-04-17	Yes	5
30011	Placebo	N03	Benelin cough sryup	Sore throat / cough				Once daily		Oral		2022-04-24	Not Ticked	No	2022-04-26	Yes	6
30011	Placebo	N03	Ibuprofen	Headache	400		mg	Once daily		Oral		2022-04-25	Not Ticked	No	2022-04-25	Yes	10
30011	Placebo	N03	Sumatryptan	Migraines	50		mg	Once daily		Oral		2022-04-25	Not Ticked	No	2022-04-25	Yes	10
30013	Active	N03	Mirtazipine	Sleep difficulties	1		mg	As required		Oral		2020-06-01	Ticked	Yes		No	
30013	Active	N03	Pantoprazole	Acid reflux	20		mg	Once daily		Oral		2020-08-28	Ticked	Yes		No	
30013	Active	N03	Ibuprofen	Headache	200		mg	As required		Oral		2022-04-12	Not Ticked	No	2022-04-12	Yes	5
30015	Active	N03	Multivitamins (Bassetts)	General health		1	capsule	Once daily		Oral		2022-01-10	Ticked	Yes		No	
40005	Active	N04	Pfizer Covid 19 booster 3rd	Covid prevention	0		ml	Once daily		Other (please specify)	intramuscular	2021-12-16	Ticked	No	2021-12-16	No	

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Participant ID	Group	Site	Concomitant Medication Name	Indication	Dose	Other dose	Units	Frequency	Other Frequency, please specify	Route	Other Route, please specify	Start Date	Pre Study	Ongoing ?	End date	Conmed used for treatment of AE/SAE?	AE no.
40005	Active	N04	None stopped multivitamins 6 weeks ago														
40005	Active	N04	Paracetamol	Toothache	500		mg	As required		Oral			Ticked	No		2022-12-16	No
60004	Placebo	N06	Atorvastatin	Cholesterol	10		mg	Once daily		Oral			Ticked	Yes			No
60004	Placebo	N06	Propanalol	Migraines headaches	40		mg	Once daily		Oral			Ticked	Yes			No
60004	Placebo	N06	Alfuzosin	Nocturia terminal dribbling urgency to use toilet.	10		mg	Once daily		Oral			Ticked	Yes			No
60004	Placebo	N06	Solifenacin	Overactive bladder	10		mg	Once daily		Oral			Ticked	Yes			No
60004	Placebo	N06	Cetirizine	Itchy feet	10		mg	Once daily		Oral			Ticked	Yes			No
60004	Placebo	N06	Sumatriptan	Headaches	100		mg	As required		Oral			Ticked	Yes			No
60004	Placebo	N06	Omeprazole	Hiatus Hernia				As required		Oral			Ticked	No			No
60009	Active	N06	Promethazine	Insomnia	25		mg	As required		Oral		2021-08-10	Ticked	Yes			No
60009	Active	N06	Omeprazole	Reflux	10		mg	As required		Oral		2021-08-15	Ticked	No		2021-10-09	No
60009	Active	N06	Rigredon	Contraception	1	1 tablet		Once daily		Oral		2017-12-15	Ticked	Yes			No
60010	Active	N06															
60014	Active	N06	Resolar prucalopride	For constipation	2		mg	Once daily		Oral			Ticked	Yes			No
60014	Active	N06	Furosemide	Edema of left leg	40	1	mg	Once daily		Oral			Ticked	Yes			No

Table 37 Concomitant therapies
Listing Population: Full (n = 15)

Participant ID	Group	Site	Type of therapy	Other type of therapy, Please specify	Frequency	Frequency: Please specify	Start Date	Pre-study?	Ongoing?
10004	Active	N01	Other (please specify)	Shiatso	Every 3 weeks		2018-07-01	Ticked	Yes
60004	Placebo	N06	Acupuncture		Other (please specify)	6-8 weeks	2021-03-01	Ticked	Yes

Patient 30015 did not complete the form

Section: Safety
Table 38AE Listings (part 1)
Details Population: Full (n = 15)

Participant ID	Group	Site	AE No.	Adverse Event Term	Date of Onset	Date of resolution	Outcome	Severity	Action Taken	Causality of IMP	Expectedness
10004	Active	N01	1	Metallic taste, in mouth in mornings after taking IMP , resolving by lunch each day , for 6 mornings.	2019-11-21	2019-11-26	Resolved no residual effects	Mild	None	Probably	Expected
10004	Active	N01	2	Headache	2019-12-12	2019-12-13	Resolved no residual effects	Mild	None	Possibly	Expected
10004	Active	N01	3	Sluggish feeling and weighed down	2019-12-12	2019-12-30	Resolved no residual effects	Mild	None	Possibly	Unexpected
10004	Active	N01	4	Cold symptoms, fever, headache, aching muscles, cough	2019-12-23	2019-12-30	Resolved no residual effects	Mild	None	Possibly	Unexpected
10004	Active	N01	5	Feeling achey	2019-12-12	2019-12-13	Resolved no residual effects	Mild	None	Possibly	Expected
10004	Active	N01	6	nausea in the morning after taking IMP resolved by lunch each day	2019-11-21	2019-11-26	Resolved no residual effects	Mild	None	Probably	Expected
10004	Active	N01	7	Tiredness in the morning after taking IMP resolved by lunch each day.	2019-11-21	2019-11-26	Resolved no residual effects	Mild	None	Probably	Expected
10006	Placebo	N01	1	Heavyhead + dizziness	2019-12-05	2019-12-08	Resolved no residual effects	Mild	None	Probably	Expected
10006	Placebo	N01	2	Diarrhoea	2019-12-17	2019-12-18	Resolved no residual effects	Mild	None	Unlikely	Unexpected
10006	Placebo	N01	3	Night sweats 'drenching'	2019-12-08	2019-12-23	Resolved no residual effects	Moderate	Participant withdrawn from treatment due to AE	Possibly	Unexpected
10006	Placebo	N01	4	Night terrors	2019-12-14	2019-12-23	Resolved no residual effects	Moderate	Participant withdrawn from treatment due to AE	Possibly	Unexpected
10006	Placebo	N01	5	Anxiety	2019-12-12	2019-12-23	Resolved no residual effects	Moderate	Participant withdrawn from treatment due to AE	Possibly	Unexpected
10019	Placebo	N01	1	Aches from cutting grass	2021-06-14	2021-06-14	Resolved no residual effects	Mild	Medication given for AE	Unlikely	Expected
10019	Placebo	N01	2	Sore throat	2021-07-09	2021-07-10	Resolved no residual effects	Mild	Medication given for AE	Possibly	Unexpected
10019	Placebo	N01	3	Aching legs worse than usual	2021-07-17	2021-07-20	Resolved no residual effects	Mild	Medication given for AE	Possibly	Unexpected
10019	Placebo	N01	4	Tested positive for MRSA at routine swab	2021-08-02	2021-08-13	Resolved no residual effects	Mild	Medication given for AE	Probably	Unexpected
10019	Placebo	N01	5	General aches	2021-08-01	2021-08-03	Resolved no residual effects	Mild	Medication given for AE	Unlikely	Unexpected
10019	Placebo	N01	6	Mild neutropenia (1.21)	2021-08-13	2021-09-03	Resolved no residual effects	Mild	None	Unlikely	Unexpected
10036	Active	N01	1	Upper respiratory tract infection	2022-04-04	2022-04-08	Resolved with residual effects	Mild	Medication given for AE	Unlikely	Unexpected

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Participant ID	Group	Site	AE No.	Adverse Event Term	Date of Onset	Date of resolution	Outcome	Severity	Action Taken	Causality of IMP	Expectedness
10036	Active	N01	2	Chest pain	2022-04-05	2022-04-23	Resolved no residual effects	Mild	Medication given for AE	Unlikely	Unexpected
10036	Active	N01	3	Testicular pain	2022-04-06	2022-04-20	Resolved no residual effects	Mild	Medication given for AE	Unlikely	Unexpected
10036	Active	N01	4	CRP out of range at visit 2 (5.53)	2022-04-13	2022-05-11	Resolved no residual effects	Mild	None	Not related	Unexpected
10036	Active	N01	5	Panic attacks/anxiety attacks at work. Not had them before. (shakiness, panic) Worst one 1.5hrs others much shorter			Ongoing (including at time of death)	Mild	None	Unlikely	Unexpected
10036	Active	N01	6	Burn left wrist 10p sized at work as chef in kitchen. Blistered.	2022-04-22	2022-05-20	Resolved no residual effects	Mild	None	Not related	Unexpected
10036	Active	N01	7	Burn right forearm. Linear 3-4 inches long.	2022-04-25	2022-05-10	Resolved no residual effects	Mild	None	Not related	Unexpected
10036	Active	N01	8	Intrusive thoughts from past - has had before but more intense this time. not self-injurious or suicidal thoughts.	2022-04-16		Ongoing (including at time of death)	Mild	None	Unlikely	Unexpected
10036	Active	N01	9	Chest pain; right sided subcostal, occasionally catches (?) on deep breathing, intermittent.	2022-04-27	2022-05-10	Resolved no residual effects	Mild	None	Not related	Unexpected
10036	Active	N01	0	Bang to head - headache, dizziness, lump, nausea, and bruising.	2022-05-14	2022-05-15	Resolved no residual effects	Mild	None	Not related	Unexpected
10036	Active	N01	1	White cell count 1.2 is out of range at visit 3 (range 3.8 - 10.8)	2022-05-10	2022-05-20	Resolved no residual effects	Mild	None	Not related	Unexpected
10036	Active	N01	2	Lymphocytes absolute out of range at visit 3 4.19 (range 0.85-4.10)	2022-05-10	2022-05-20	Resolved no residual effects	Mild	None	Not related	Unexpected
10036	Active	N01	3	Cholesterol, total out of range at visit 3 5.80 (range 0.00 - 5.15)	2022-05-10		Ongoing (including at time of death)	Mild	None	Not related	Unexpected
10036	Active	N01	4	Cholesterol, total out of range at screening 5.35 (range 0.00 - 5.15)	2022-02-07	2022-03-16	Resolved no residual effects	Mild	None	Not related	Unexpected
10038	Placebo	N01	1	Red cell count out of range at visit 1 4.3 (ref range 4.4 - 5.8)	2022-03-22	2022-05-22	Resolved no residual effects	Not applicable	None	Not related	Unexpected
10038	Placebo	N01	2	Sodium out of range at visit 1 133 (ref range 135-146)	2022-03-22	2022-04-19	Resolved no residual effects	Not applicable	None	Not related	Unexpected
10038	Placebo	N01	3	Cholesterol out of range at visit 1 5.3 (ref range 0.00-5.15)	2022-03-22		Ongoing (including at time of death)	Not applicable	None	Not related	Unexpected
10038	Placebo	N01	4	Headaches (slightly more than normal)	2022-03-23		Ongoing (including at time of death)	Mild	None	Unlikely	Expected
10038	Placebo	N01	5	Pulled muscles in neck and lower back x 2	2022-04-01	2022-04-18	Resolved no residual effects	Mild	None	Unlikely	Unexpected
10038	Placebo	N01	6	Palpitations & anxiety	2022-04-04	2022-04-05	Resolved no residual effects	Mild	None	Unlikely	Unexpected
10038	Placebo	N01	7	Constipation	2022-02-01		Ongoing (including at time of death)	Mild	None	Unlikely	Unexpected

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Participant ID	Group	Site	AE No.	Adverse Event Term	Date of Onset	Date of resolution	Outcome	Severity	Action Taken	Causality of IMP	Expectedness
10038	Placebo	N01	8	Red cell count out of range visit 2 4.3 (ref range 4.4 - 5.8)	2022-04-19	2022-05-22	Resolved no residual effects	Not applicable	None	Not related	Unexpected
10038	Placebo	N01	9	Monocytes out of range at visit 2 12.9 (ref range 0.0 - 12.0)	2022-04-19	2022-05-22	Resolved no residual effects	Not applicable	None	Unlikely	Unexpected
10038	Placebo	N01	0	Cholesterol out of range at visit 2 5.7 (ref range 0.0 - 5.15)	2022-04-19		Ongoing (including at time of death)	Not applicable	None	Not related	Unexpected
10038	Placebo	N01	1	Sleep disturbance (3 times in 2 weeks)	2022-04-20		Ongoing (including at time of death)	Mild	None	Unlikely	Unexpected
10038	Placebo	N01	2	Congestion due to bad reaction to cow parsley	2022-04-23	2022-04-23	Resolved no residual effects	Mild	None	Not related	Unexpected
10038	Placebo	N01	3	Muscle fatigue following bike ride	2022-05-09	2022-05-10	Resolved no residual effects	Mild	None	Not related	Unexpected
10038	Placebo	N01	4	Anxiety stress, heart racing prior to job interview	2022-05-16	2022-05-17	Resolved no residual effects	Mild	None	Unlikely	Unexpected
30002	Active	N03	1	Clinically significant cholesterol from baseline blood results	2021-06-21		Unknown	Not applicable	None	Not related	Unexpected
30002	Active	N03	2	Abnormal clinically significant results of urinalysis at baseline	2021-06-21		Unknown	Not applicable	None	Not related	Unexpected
30002	Active	N03	3	Cold symptoms with blocked nose and slight headache	2021-06-27	2021-06-27	Resolved no residual effects	Mild	Medication given for AE	Not related	Unexpected
30002	Active	N03	4	Constipation	2021-07-30	2021-08-06	Resolved no residual effects	Moderate	Medication given for AE	Unlikely	Unexpected
30006	Placebo	N03	1	Rash lower back/top of buttocks. Itchy.	2021-11-02	2021-12-04	Unknown	Mild	None	Possibly	Unexpected
30006	Placebo	N03	2	Rash - sore + itchy. Feels like a bruise to touch. Right hand side lower armpit/breast	2021-12-12	2021-12-16	Unknown	Mild	None	Possibly	Unexpected
30006	Placebo	N03	3	High levels of PH in urine strong urinalysis result PH: 8.5	2021-12-13	2021-12-20	Unknown	Mild	None	Unlikely	Unexpected
30006	Placebo	N03	4	cholesterol out of range (7.45) deemed clinically significant	2021-10-19		Unknown	Mild	None	Not related	Unexpected
30006	Placebo	N03	5	cholesterol total of range (6.70) deemed clinically significant	2021-11-16		Ongoing (including at time of death)	Mild	None	Not related	Unexpected
30006	Placebo	N03	6	cholesterol total out of range (7.30) clinically significant	2021-12-03		Ongoing (including at time of death)	Mild	None	Not related	Unexpected
30006	Placebo	N03	7	cholesterol total out of range (7.05) clinically significant	2022-01-20		Ongoing (including at time of death)	Mild	None	Not related	Unexpected
30006	Placebo	N03	8	High levels of bilirubin in urine.	2021-09-16		Unknown	Not applicable	None	Not related	Unexpected
30011	Placebo	N03	1	Migraines	2022-02-25	2022-02-27	Resolved no residual effects	Moderate	None	Possibly	Expected

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Participant ID	Group	Site	AE No.	Adverse Event Term	Date of Onset	Date of resolution	Outcome	Severity	Action Taken	Causality of IMP	Expectedness
30011	Placebo	N03	2	Headaches	2022-03-04	2022-03-05	Resolved no residual effects	Mild	None	Possibly	Expected
30011	Placebo	N03	3	Headache	2022-03-18	2022-03-18	Resolved no residual effects	Mild	None	Possibly	Expected
30011	Placebo	N03	4	Mild Headache	2022-03-27	2022-03-27	Resolved no residual effects	Mild	None	Possibly	Expected
30011	Placebo	N03	5	Covid (testing positive)	2022-04-05	2022-04-14	Resolved no residual effects	Moderate	None	Not related	Unexpected
30011	Placebo	N03	6	Covid symptoms (fatigue, persistent cough)	2022-04-09	2022-04-26	Ongoing (including at time of death)	Severe	None	Not related	Unexpected
30011	Placebo	N03	7	Eosinophils absolute (0.04 g/L)	2022-01-12		Unknown	Mild	None	Not related	Unexpected
30011	Placebo	N03	8	Cholesterol total (5.45 mmol/L)	2022-01-12		Unknown	Mild	None	Not related	Unexpected
30011	Placebo	N03	9	Out of range calcium levels (2.08 mmol/L)	2022-02-22		Unknown	Mild	None	Not related	Unexpected
30011	Placebo	N03	0	Migraine	2022-04-25	2022-04-25	Resolved no residual effects	Mild	None	Possibly	Expected
30013	Active	N03	1	Flu symptoms - fever, cough, headaches	2022-02-16	2022-02-23	Resolved no residual effects	Mild	None	Not related	Unexpected
30013	Active	N03	2	Dizziness - evening time (2-3 hours)	2022-03-13	2022-03-13	Resolved no residual effects	Mild	None	Unlikely	Unexpected
30013	Active	N03	3	Headache (15 - 20 mins) - mild pain level	2022-04-06	2022-04-06	Resolved with residual effects	Mild	None	Possibly	Unexpected
30013	Active	N03	4	Headache (sudden onset, pain moderate level)	2022-04-05	2022-04-05	Resolved no residual effects	Moderate	None	Possibly	Expected
30013	Active	N03	5	Headache - 1 hour (severe pain level, threw up due to pain, took ibuprofen)	2022-04-12	2022-04-12	Resolved no residual effects	Severe	Medication given for AE	Possibly	Expected
30013	Active	N03	6	Dizziness, nausea + ears ringing due to blood draw	2022-04-25	2022-04-25	Resolved no residual effects	Mild	None	Not related	Unexpected
30013	Active	N03	7	Out of range CRP (8.48 mg/L)	2022-01-26		Unknown	Not applicable	None	Not related	Unexpected
30013	Active	N03	8	Out of range CO2 (19 mmol/L)	2022-01-26		Unknown	Not applicable	None	Not related	Unexpected
30013	Active	N03	9	Out of range phosphorous (1.5mmol/L)	2022-01-26		Unknown	Not applicable	None	Not related	Unexpected
30013	Active	N03	0	Out of range CRP 6.78 mg/L	2022-03-02		Unknown	Not applicable	None	Not related	Unexpected
30013	Active	N03	1	Out of range uric acid in bloods 460 umol/L	2022-03-02		Unknown	Not applicable	None	Not related	Unexpected
30013	Active	N03	2	Out of range Platelet Count in bloods 455 gi/l	2022-05-13		Unknown	Not applicable	None	Not related	Unexpected
30013	Active	N03	3	out of range CPK (578 u/l)	2022-05-13		Unknown	Not applicable	None	Not related	Unexpected

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Participant ID	Group	Site	AE No.	Adverse Event Term	Date of Onset	Date of resolution	Outcome	Severity	Action Taken	Causality of IMP	Expectedness
30013	Active	N03	4	out of range Phosphorous inorganic 1.55 mmol/l	2022-05-13		Unknown	Not applicable	None	Not related	Unexpected
30015	Active	N03	1	Headaches (short lasting)	2022-03-15	2022-03-15	Resolved no residual effects	Mild	None	Not related	Expected
30015	Active	N03	2	Rash on left wrist	2022-04-02	2022-04-16	Resolved no residual effects	Mild	None	Possibly	Expected
30015	Active	N03	3	Fainting during blood collection at visit 1	2022-04-04	2022-04-04	Resolved with residual effects	Severe	None	Not related	Unexpected
30015	Active	N03	4	Hot flush, 30 mins after taking IMP	2022-04-06	2022-04-06	Resolved no residual effects	Mild	None	Possibly	Unexpected
30015	Active	N03	5	Cold symptoms (congested, headaches)	2022-04-21	2022-04-27	Resolved no residual effects	Mild	None	Unlikely	Unexpected
30015	Active	N03	6	Mild rash on wrist	2022-04-27		Ongoing (including at time of death)	Mild	None	Definitely	Expected
30015	Active	N03	7	Panic attack at work 30 mins	2022-04-28	2022-04-28	Resolved no residual effects	Mild	None	Not related	Unexpected
30015	Active	N03	8	Panic attack (during test and family triggered)	2022-05-03	2022-05-03	Resolved no residual effects	Mild	None	Not related	Unexpected
30015	Active	N03	9	Fatigued and low energy and couldn't get up until midday some days.	2022-06-01	2022-06-09	Resolved with residual effects	Moderate	None	Unlikely	Unexpected
30015	Active	N03	0	low mood	2022-06-01	2022-06-09	Resolved with residual effects	Moderate	None	Unlikely	Unexpected
40005	Active	N04	1	Toothache			Resolved no residual effects	Mild	Medication given for AE	Not related	Unexpected
40005	Active	N04	2	Urine stick positive for possible urine tract infection	2022-04-11	2022-04-11	Resolved no residual effects	Mild	None	Unlikely	Unexpected
40005	Active	N04	3	Frequent urination	2022-04-08		Resolved no residual effects	Mild	None	Unlikely	Unexpected
40005	Active	N04	4	abnormal HR findings	2022-02-10	2022-04-19	Unknown	Mild	None	Not related	Unexpected
60004	Placebo	N06	1	Screening bloods out of normal range. CRP - 5.84 mg/L	2021-09-09	2021-11-08	Resolved no residual effects	Not applicable	None	Not related	
60004	Placebo	N06	2	Carbon dioxide - 19 mmol/L	2021-09-09	2021-11-08	Resolved no residual effects	Not applicable	None	Not related	
60004	Placebo	N06	3	Creatinine enz - 66.3 umol/L	2021-09-09	2021-12-14	Resolved no residual effects	Not applicable	None	Not related	
60004	Placebo	N06	4	Cholesterol 6.2 mmol/L	2021-09-09		Ongoing (including at time of death)	Not applicable	None	Not related	
60004	Placebo	N06	5	Uric acid 220 umol/L	2021-09-09	2021-12-06	Resolved no residual effects	Not applicable	None	Not related	
60004	Placebo	N06	6	Migraine - following baseline visit, onset before taking first dose of medication	2021-10-12	2021-10-13	Resolved no residual effects	Mild	None	Not related	Unexpected
60004	Placebo	N06	7	Heartburn - participant has suffered regularly with heartburn	2021-10-13	2021-10-14	Resolved no residual effects	Mild	None	Not related	Unexpected

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Participant ID	Group	Site	AE No.	Adverse Event Term	Date of Onset	Date of resolution	Outcome	Severity	Action Taken	Causality of IMP	Expectedness
60009	Active	N06	1	Few days after starting medication participant noted a flare up in spot, more than average for participant	2021-11-12		Ongoing (including at time of death)	Mild	None	Possibly	Unexpected
60014	Active	N06	1	Screening bloods cholesterol 8.5mmol/L	2022-02-25		Ongoing (including at time of death)	Mild	None	Not related	
60014	Active	N06	2	Screening bloods GGT 51 U/L	2022-02-25	2022-03-28	Resolved no residual effects	Mild	None	Not related	
60014	Active	N06	3	CRP bloods 6.82mg/L (visit 2)	2022-04-29	2022-05-24	Resolved no residual effects	Mild	None	Not related	
60014	Active	N06	4	Niggling pains and shooting pains down both legs. Fleeting pains, felt like she had potentially stretched her ligaments while gardening.	2022-05-03	2022-05-05	Resolved no residual effects	Mild	None	Not related	Unexpected

Patient 60010 did not report any adverse events

Table 39AE Listings (part 2)
MedDRA coding Population: Full (n = 15)

Participant ID	AE No.	MEDRA_CODE	MedDRA SOC term	MedDRA PT code	MedDRA PT term
10004	1	10017947	Gastrointestinal disorders	10082490	taste disorder
10004	2	10029205	nervous system disorder	10019211	Headache
10004	3	10037175	Psychiatric Disorders	10012374	Depressed mood
10004	4	10018065	General Disorders and administration site disorders	10018084	Generalised Illnesses.
10004	5	10018065	General Disorders and administration site disorders	10000424	Ache
10004	6	10017947	Gastrointestinal disorders	10028813	Nausea
10004	7	10018065	General Disorders and administration site disorders	10016256	Fatigue
10006	1	10018065	General Disorders and administration site disorder	10025482	Malaise
10006	2	10017947	Gastrointestinal Disorders	10012735	Diarrhoea
10006	3	10018065	General Disorders and administration site disorders	10029410	Night Sweats
10006	4	10037175	Psychiatric Disorders	10041010	Sleep terror
10006	5	10037175	Psychiatric Disorders	10002855	Anxiety Disorders and Symptoms
10019	1	10018065	General Disorders and administration site disorders	10000424	Ache
10019	2	10038738	Respiratory, thoracic and mediastinal disorders	10068319	Oropharyngeal pain
10019	3	10018065	General Disorders and administration site disorders	10000424	ache
10019	4	10022891	Investigations	10070052	Staphylococcus test positive
10019	5	10018065	General Disorders and administration site disorders	10000424	Ache
10019	6	10022891	Investigations	10029354	Neutropenia
10036	1	10021881	Infections and infestation	10047482	Viral upper respiratory tract infection
10036	2	10018065	General disorders and administration site conditions	10007489	chest pain
10036	3	10038604	Reproductive system and breast disorders	10043345	testicular pain
10036	4	10022891	investigations	10006285	C-reactive protein increased
10036	5	10037175	Psychiatric disorders	10033664	Panic Attack
10036	6	10022117	Injury, poisoning and procedural complications	10053615	Thermal Burn
10036	7	10022117	Injury, poisoning and procedural complications	10053615	Thermal Burn
10036	8	10037175	Psychiatric disorders	10077275	Intrusive thoughts
10036	9	10018065	General disorders and administration site conditions	10008479	chest pain
10036	0	10022117	Injury, poisoning and procedural complications	10010254	concussion
10036	1	10022891	investigations	10047942	White blood cell count decreased
10036	2	10022891	investigations	10018857	Haematology investigations (incl blood groups)
10036	3	10022891	investigations	10005425	Blood cholesterol increased
10036	4	10022891	investigations	10005425	Blood cholesterol increased
10038	1	10022891	Investigations	10038153	Red blood cell count decreased
10038	2	10022891	Investigations	10005802	Blood sodium decreased
10038	3	10022891	Investigations	10005425	Blood cholesterol increased
10038	4	10029205	Nervous system disorders	10019211	Headache
10038	5	10028395	Muscle disorders	10018089	Generalised muscle aches
10038	6	10037175	Anxiety	10002855	Anxiety
10038	7	10017947	Gastrointestinal disorders	10010774	Constipation
10038	8	10022891	Investigations	10038153	Red blood cell count decreased
10038	9	10022891	Investigations	10061293	Monocyte count abnormal
10038	0	10022891	Investigations	10005425	Blood cholesterol increased
10038	1	10037175	Psychiatric disorders	10040984	Sleep disorders and disturbances
10038	2	10038738	Respiratory, thoracic and mediastinal disorders	10028735	Nasal congestion

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Participant ID	AE No.	MEDRA_CODE	MedDRA SOC term	MedDRA PT code	MedDRA PT term
10038	3	10028395	Muscle disorder	10018089	Generalised muscle aches
10038	4	10037175	Psychiatric disorders	10002855	Anxiety
30002	1	10022891	investigations	10005425	Blood cholesterol increased
30002	2	10022891	investigations	10062226	Urine analysis abnormal
30002	3	10018065	General Disorders and administration site disorders	10018084	generalised illness
30002	4	10017947	Gastrointestinal Disorders	10010774	constipation
30006	1	10040785	Skin and subcutaneous tissue disorders	10037844	rash
30006	2	10040785	Skin and subcutaneous tissue disorders	10037844	rash
30006	3	10022891	investigations	10034795	ph urine increased.
30006	4	10022891	investigations	10005425	blood cholesterol increased
30006	5	10022891	investigations	10005425	blood cholesterol increased
30006	6	10022891	investigations	10005425	blood cholesterol increased
30006	7	10022891	investigations	10005425	blood cholesterol increased.
30006	8	10022891	investigations	10005364	Blood Bilirubin inceased
30011	1	10029205	Nervous system disorders	10027599	Migraine
30011	2	10029205	Nervous system disorders	10019211	headache
30011	3	10029205	Nervous system disorders	10019211	headache
30011	4	10029205	Nervous system disorders	10019211	headache
30011	5	10021881	Infections and infestations	10084268	covid 19
30011	6	10021881	Infections and infestations	10047482	Viral upper respiratory tract infection
30011	7	10022891	Investigations	10061125	Eosinophil count abnormal
30011	8	10022891	Investigations	10005425	Blood cholesterol increased
30011	9	10022891	Investigations	10005395	Blood calcium decreased
30011	0	10029205	Nervous system disorders	10027599	Migraine
30013	1	10021881	Infections and infestation	10047482	R Viral upper respiratory tract infection
30013	2	10013993	Ear and labyrinth disorders	10079170	Persistent postural-perceptual dizziness
30013	3	10029205	Nervous system disorders	10019211	Headache
30013	4	10029205	Nervous system disorders	10019211	Headache
30013	5	10029205	Nervous system disorders	10019211	Headache
30013	6	10013993	Ear and labyrinth disorders	10079170	Persistent postural-perceptual dizziness
30013	7	10022891	Investigations	10006825	c-reactive protein increased
30013	8	10022891	Investigations	10007223	Carbon dioxide decreased
30013	9	10022891	Investigations	10050196	Blood phosphorus increased
30013	0	10022891	Investigations	10006825	c-reactive protein increased
30013	1	10022891	Investigations	10005861	Blood uric acid increased OR
30013	2	10022891	investigations	10051608	Platelet count increased
30013	3	10022891	investigations	10005470	Blood creatine phosphokinase BB increased
30013	4	10022891	investigations	10050196	Blood Phosphorus increased
30015	1	10029205	Nervous system disorders	10019211	headache
30015	2	10040785	Skin and subcutaneous tissue disorders	10037844	rash
30015	3	10037175	Psychiatric disorders	10042772	Syncope
30015	4	10018065	General disorders and administration site disorders	10060800	hot flush
30015	5	10018065	General disorders and administration site disorders	10018084	Generalised illness
30015	6	10018065	Skin and subcutaneous tissue disorders	10037844	rash
30015	7	10040785	Psychiatric disorders	10033664	Panic Attack
30015	8	10037175	Psychiatric disorders	10033664	Panic Attack
30015	9	10018065	General disorders and administration site disorders	10016256	fatigue

Participant ID	AE No.	MEDRA_CODE	MedDRA SOC term	MedDRA PT code	MedDRA PT term
30015	0	10037175	Psychiatric disorders	10012374	Depressed mood disorders and disturbances
40005	1	10017947	Gastrointestinal disorders	10044055	Toothache
40005	2	10038359	Renal and urinary disorders	10046511	Urinalysis abnormal NOS
40005	3	10038359	Renal and urinary disorders	10036018	Pollakiuria
40005	4	10022891	investigations	10019300	HR Abnormal
60004	1	10022891	investigations	10006825	C-reactive protein increased
60004	2	10022891	investigations	10020952	hypocapnia
60004	3	10022891	investigations	10005482	Blood creatine increased
60004	4	10022891	investigations	10005245	Blood Chloestrol increased
60004	5	10022891	investigations	10005861	Blood uric acid increased.
60004	6	10029205	nervous system disorder	10027599	migraine
60004	7	10017947	Gastrointestinal Disorders	10082500	gastroesophageal burn
60009	1	10040785	Skin and subcutaneous tissue disorders	10000496	Acne
60014	1	10022891	investigations	10005425	blood cholesterol increased
60014	2	10022891	investigations	10017693	Gamma-gluteanyltransferiase increased
60014	3	10022891	investigations	10006825	c-reactive protein increased
60014	4	10018065	General Disorders and administration site disorders	10033371	pain

Table 40AE summary
Population: Full (n = 15)

Treatment	Subjects with SAE	Subjects with AE	Deaths	Patients Exposed
Active	0	8	0	9
Placebo	0	6	0	6

Table 41AE PT detailed breakdown
PT term Population: Full (n = 15)

System Organ Class	Preferred Term	Active-Occurrences	Active-Subjects	Placebo-Occurrences	Placebo-Subjects
Blood and lymphatic system disorders	Neutropenia	0	0	1	1
Gastrointestinal disorders	Constipation	1	1	1	1
	Diarrhoea	0	0	1	1
	Nausea	1	1	0	0
	Toothache	1	1	0	0
General disorders and administration site conditions	Chest pain	1	1	0	0
	Fatigue	2	2	0	0
	Illness	3	3	0	0
	Malaise	0	0	1	1
	Pain	2	2	3	1
Infections and infestations	COVID-19	0	0	1	1
	Viral upper respiratory tract infection	2	2	1	1
Injury, poisoning and procedural complications	Burn oesophageal	0	0	1	1
	Burns second degree	0	0	1	1
	Concussion	1	1	0	0
	Post procedural haematoma	1	1	0	0
	Thermal burn	2	1	0	0
Investigations	Blood bilirubin increased	0	0	1	1
	Blood calcium decreased	0	0	1	1
	Blood cholesterol increased	4	3	7	3
	Blood creatine phosphokinase increased	1	1	0	0
	Blood creatinine decreased	0	0	1	1
	Blood phosphorus increased	2	1	0	0
	Blood sodium decreased	0	0	1	1
	Blood uric acid increased	1	1	1	1
	C-reactive protein increased	3	2	1	1
	Carbon dioxide decreased	1	1	0	0
	Eosinophil count abnormal	0	0	1	1
	Gamma-glutamyltransferase increased	1	1	0	0
	Heart rate abnormal	1	1	0	0

System Organ Class	Preferred Term	Active-Occurrences	Active-Subjects	Placebo-Occurrences	Placebo-Subjects
	Monocyte count abnormal	0	0	1	1
	Platelet count increased	1	1	0	0
	Red blood cell count decreased	0	0	2	1
	Staphylococcus test positive	0	0	1	1
	Urine analysis abnormal	2	2	0	0
	White blood cell count decreased	1	1	0	0
	pH urine increased	0	0	1	1
Musculoskeletal and connective tissue disorders	Myalgia	0	0	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast neoplasm	1	1	0	0
Nervous system disorders	Cervix carcinoma stage I	1	1	0	0
	Headache	5	3	4	2
	Migraine	0	0	3	2
	Persistent postural-perceptual dizziness	2	1	0	0
	Syncope	1	1	0	0
Psychiatric disorders	Taste disorder	1	1	0	0
	Anxiety	0	0	3	2
	Depressed mood	2	2	0	0
	Intrusive thoughts	1	1	0	0
	Panic attack	3	2	0	0
	Sleep disorder	0	0	1	1
	Sleep terror	0	0	1	1
Renal and urinary disorders	Pollakiuria	1	1	0	0
Reproductive system and breast disorders	Testicular pain	1	1	0	0
Respiratory, thoracic and mediastinal disorders	Hypocapnia	0	0	1	1
	Nasal congestion	0	0	1	1
	Oropharyngeal pain	0	0	1	1
Skin and subcutaneous tissue disorders	Acne	1	1	0	0
	Night sweats	0	0	1	1
	Rash	2	1	2	1
Vascular disorders	Hot flush	1	1	0	0
Total		58	49	50	37

Table 42AE SOC grouping
SOC term Population: Full (n = 15)

System Organ Class	Placebo	Active
Blood and lymphatic system disorders	17% (1/6)	-
Gastrointestinal disorders	33% (2/6)	33% (3/9)
General disorders and administration site conditions	33% (2/6)	56% (5/9)
Infections and infestations	17% (1/6)	22% (2/9)
Injury, poisoning and procedural complications	17% (1/6)	11% (1/9)
Investigations	83% (5/6)	56% (5/9)
Musculoskeletal and connective tissue disorders	17% (1/6)	-
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-	11% (1/9)
Nervous system disorders	50% (3/6)	33% (3/9)
Psychiatric disorders	33% (2/6)	33% (3/9)
Renal and urinary disorders	-	11% (1/9)
Reproductive system and breast disorders	-	11% (1/9)
Respiratory, thoracic and mediastinal disorders	50% (3/6)	-
Skin and subcutaneous tissue disorders	33% (2/6)	22% (2/9)
Vascular disorders	-	11% (1/9)

Figure 7AE SOC grouping - Relative Risk
SOC term Population: Full (n = 15)

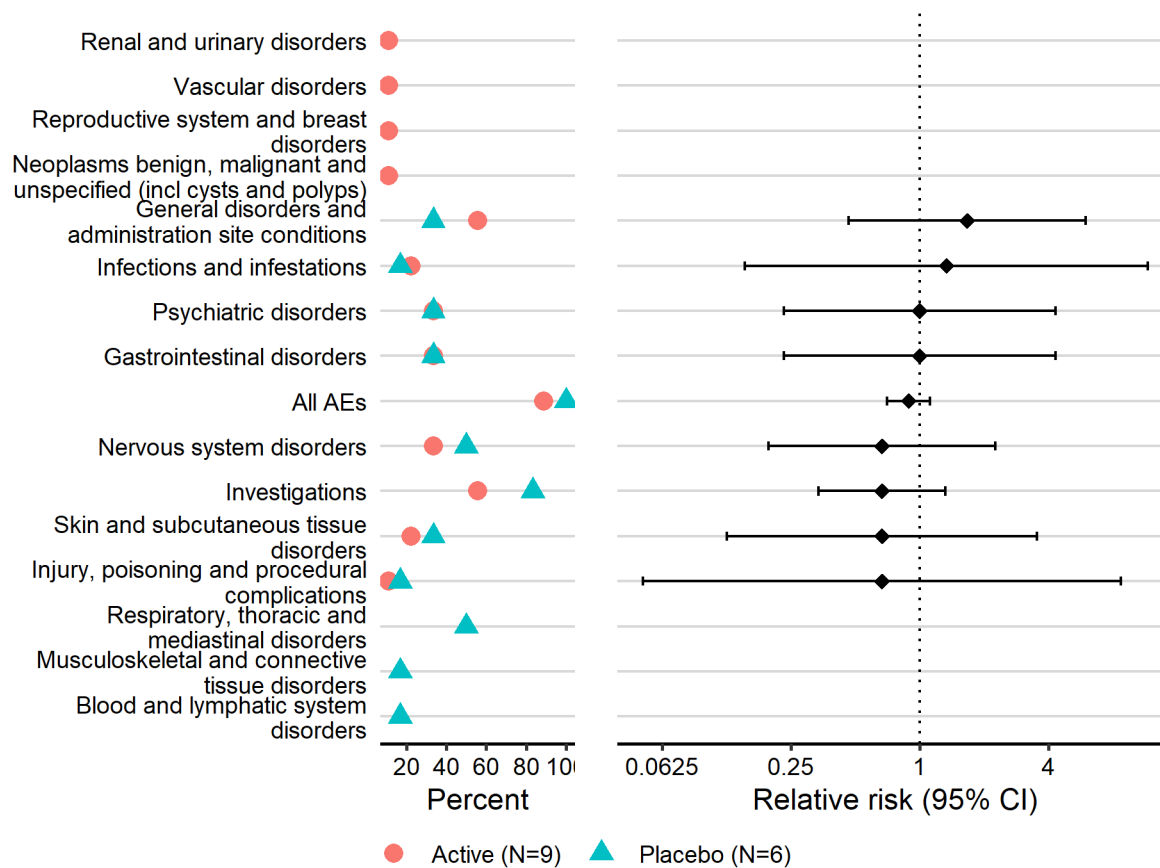


Table 43SAEs
Listing Population: Full (n = 15)
Note
No Serious Adverse Events reported

Table 44Special reporting situations Listing Population: Full (n = 15)
Note
No Special Reporting Situations reported

Table 45Pregnancies
Listing Population: Full (n = 15)

Note

No pregnancies reported

Section: Data
Table 46 Summary of Data Files

name	file	folder	mod_time
data0	ATP_TRIAL20230505_SCREENING_to_FOLLOWUP.csv	V:/DOWNLOADS/ATP/DataDownload20230505	2023-05-05 10:32:41
clu0	ATP_TRIAL20230505_SCREENING_to_FOLLOWUP_CLU.csv	V:/DOWNLOADS/ATP/DataDownload20230505	2023-05-05 10:32:41
dlu0	ATP_TRIAL20230505_SCREENING_to_FOLLOWUP_DLU.csv	V:/DOWNLOADS/ATP/DataDownload20230505	2023-05-05 10:32:41
data1	ATP_TRIAL20230505_UNSCHEДУLED_to_RESCREENING.csv	V:/DOWNLOADS/ATP/DataDownload20230505	2023-05-05 10:40:33
clu1	ATP_TRIAL20230505_UNSCHEДУLED_to_RESCREENING_CLU.csv	V:/DOWNLOADS/ATP/DataDownload20230505	2023-05-05 10:40:33
dlu1	ATP_TRIAL20230505_UNSCHEДУLED_to_RESCREENING_DLU.csv	V:/DOWNLOADS/ATP/DataDownload20230505	2023-05-05 10:40:33
meta_table	meta_table.xlsx	V:/STATISTICS/STUDY FOLDER/Core/ATP/Statistics/3 Analysis/Final/V1/data	2023-05-11 11:51:38
sites	site_information.csv	V:/STATISTICS/STUDY FOLDER/Core/ATP/Statistics/3 Analysis/Final/V1/data	2023-05-11 11:45:55
llt	llt.asc	V:/STATISTICS/STUDY FOLDER/Core/ATP/Statistics/3 Analysis/Final/V1/data/medra_V251	2022-06-20 14:24:18
pt	pt.asc	V:/STATISTICS/STUDY FOLDER/Core/ATP/Statistics/3 Analysis/Final/V1/data/medra_V251	2022-06-20 14:24:18
soc	soc.asc	V:/STATISTICS/STUDY FOLDER/Core/ATP/Statistics/3 Analysis/Final/V1/data/medra_V251	2022-06-20 14:24:18
rand_list	codelist.csv	V:/DOWNLOADS/ATP/Randomisation_Archive/atp_archive/csv	2022-07-21 10:35:28