On line Appendix for RCT of Group Psychoeducation versus Group Support

Table A1. Sessions of group psychoeducation treatment in bipolar disorder

Session no.	Topic
1	Introduction to the group and defining bipolar disorder?
2	What causes and triggers bipolar disorder
3	Symptoms 1: mania and hypomania
4	Symptoms 2: depression and mixed episodes
5	Evolution of bipolar disorder and the future
6	Treatment 1: mood stabilisers
7	Treatment 2: antimanic drugs
8	Treatment 3: antidepressants
9	Pregnancy, genetic counselling and effects on families
10	Prescribed drugs and alternative therapies
11	Risks associated with treatment withdrawal
12	Alcohol, smoking, diet and street drugs
13	Early detection of mania and hypomania 1
14	Early detection of mania and hypomania 2
15	Early detection of depression and mixed episodes 1
16	Early detection of depression and mixed episodes 2
17	What to do when a new phase is detected
18	Regularity of habits
19	Stress control techniques
20	Problem solving strategies
21	Finalisation of stay well plan and closure

Table A2. Session content of peer support groups in bipolar disorder.

Topics covered	No. groups, *n* = 11 (% groups)
Topic covered also by psychoeducation programme	
Introduction to the group and defining bipolar disorder	10 (91)
What causes and triggers bipolar disorder	10 (91)
Symptoms 1: mania and hypomania	11 (100)
Symptoms 2: depression and mixed episodes	11 (100)
Evolution of bipolar disorder and the future	1 (9)
Treatment 1: mood stabilisers	0
Treatment 2: antimanic drugs	0
Treatment 3: antidepressants	0
Pregnancy, genetic counselling and effects on families	5 (45)
Prescribed drugs and alternative therapies	8 (73)
Risks associated with treatment withdrawal	3 (27)
Alcohol, smoking, diet and street drugs	5 (45)
Early detection of mania and hypomania	6 (55)
Early detection of depression and mixed episodes	6 (55)
What to do when a new phase is detected	6 (55)
Regularity of habits	8 (73)
Stress control techniques	9 (82)
Problem solving strategies	9 (82)
Finalisation of stay well plan and closure	7 (64)
Additional topics covered by peer support	
Services	9 (82)
Hospital	5 (45)
Benefits and welfare	9 (82)
Finances and debt	4 (36)
Emotions	8 (73)
Relationships (family and friends)	8 (73)
Positivity	5 (45)
The Self (personal experience/life stories)	8 (73)
The Self (identity and perception)	5 (45)
Stigma	5 (45)
Anxiety	4 (36)
Non-anxiety mental comorbidity and physical health	4 (36)
Religion and spirituality	4 (36)
Media	4 (36)

Table A3. Statistical analysis method for secondary symptomatic and functional outcomes.

For each person the average of their weekly scores over each 16- (or alternative) week interval post randomisation was calculated. Inferential analyses of the symptom scores (assumed to be normally distributed) were based on linear mixed effects (LME, also known as random effects or random coefficient) models which include two parts: a) fixed main effects (or average response) and b) random effect terms accounting for the fact that measurements taken on the same subject over time are likely to be correlated. For the fixed part each regression coefficient was assumed to take the same fixed value for all people whereas the random effects are effects assumed to vary from person to person. Because treatment effect interpretation is easier for models with a linear predictor compared to models with a non-linear predictor the former are preferred.

Up to two longitudinal LME models were fitted to the averaged scores with each model including the following covariates for the average response part of the model: time (as a continuous variable based on date the LIFE was completed relative to randomisation date), treatment arm along with the covariates considered for the Cox model fitted to the primary outcome (i.e., sex, number of previous episodes and wave). The baseline value for each outcome was added. If this term is constant then this covariate was not included in the model. Based on available data, time was centered to provide an estimate of the treatment effect and treatment by time effect. We also specified a pair of correlated random effects: an intercept and linear slope where subjects have their own slope representing individual subjects' variations from the average slope. In addition, therapy group was included as a random effect subject to model fitting constraints. Inclusion of therapy group took account of group clustering effects. The models, in decreasing order of complexity, were as follows:

Model 1: As there may be a faster rate of recovery/decline in one group than the other a time with intervention arm interaction was fitted. This main effects interaction between time and treatment arm was tested for statistical significance.

Model 2: If the interaction in Model 1 was not significant then this term was omitted and Model 2 was fitted to test whether there is a systematic effect of treatment arm.

If there were convergence problems when fitting the models then the random slope and/or random therapy group terms was omitted from the model. Restricted maximum likelihood were used to fit the models. Based on the final model the estimated treatment difference between the two groups, 95% confidence interval and P-values were tabulated. This was based on a wald test i.e. the estimated coefficient divided by the standard error of the coefficient. Models included the fixed effect covariates: baseline measure, treatment group, centred time from randomisation to each assessment at 16-week intervals, the interaction between the baseline score and centred time in months, gender and number of previous bipolar episodes.

Of note, by using maximum likelihood for these models, "Missing At Random" was assumed for drop-out i.e., missing outcome data was conditional on observed data. Under this assumption it was assumed that future behaviour, given the past, was the same for all,

whether a participant dropped out or not. This allowed distributional information to be "borrowed" from those who remained on the trial and applied to those who drop-out given they had the same covariate set up until the time of dropout. Therefore, the estimate of treatment effect is what would be seen if all participants had remained on the study until the end. The distributional assumptions of normality were assessed at the time-point, subject and therapy group level. Where there was evidence of non-normality outcome data was transformed. Particular observations that had unusually large influence on the results were identified and the analysis repeated with them omitted.

Table A4. Interview-rated symptom secondary outcome measures by time in psychoeducation and peer support groups in bipolar disorder.

Time point	Psychoeducation (*n* = 153)						Peer support (*n* = 151)					
	M	SD	Med	Min	Max	*n*	M	SD	Med	Min	Max	*n*
SCID LIFE weekly mean score for depression over 16-week period												
0	1.83	0.85	1.75	1.00	4.00	152	1.84	0.87	1.75	1.00	4.25	148
16	1.84	0.88	1.58	1.00	4.87	131	2.00	1.08	1.59	1.00	5.92	123
32	2.18	1.14	1.91	1.00	5.18	124	2.00	1.01	1.80	1.00	6.00	118
48	1.89	1.07	1.56	1.00	5.88	117	1.94	1.03	1.69	1.00	6.00	111
64	1.83	1.05	1.44	1.00	6.00	113	2.00	1.05	1.73	1.00	5.00	105
80	1.85	1.05	1.41	1.00	5.50	114	2.06	1.00	1.82	1.00	4.75	98
96	1.84	1.15	1.25	1.00	5.39	107	1.94	1.00	1.59	1.00	5.24	98
SCID LIFE weekly mean score for mania over 16-week period												
0	1.20	0.48	1.00	1.00	4.50	152	1.28	0.54	1.00	1.00	4.00	148
16	1.24	0.41	1.00	1.00	3.63	131	1.27	0.49	1.00	1.00	4.00	123
32	1.22	0.44	1.00	1.00	3.63	124	1.28	0.44	1.00	1.00	3.00	118
48	1.17	0.42	1.00	1.00	3.88	117	1.24	0.43	1.00	1.00	3.33	111
64	1.22	0.59	1.00	1.00	4.60	113	1.30	0.61	1.00	1.00	5.00	105
80	1.23	0.59	1.00	1.00	5.00	114	1.16	0.33	1.00	1.00	2.78	98
96	1.21	0.46	1.00	1.00	3.50	107	1.36	0.73	1.00	1.00	4.36	98
Hamilton Depression Rating Scale (HAMD)												
0	6.59	5.18	7.00	0	27	152	6.17	5.00	5.00	0	26	145
16	7.04	7.15	4.50	0	30	131	7.58	6.29	6.63	0	24	123
32	7.00	7.17	5.00	0	35	122	8.18	7.26	6.00	0	33	119
48	6.09	6.91	4.00	0	32	117	7.19	7.71	5.00	0	36	111
64	6.73	6.71	4.38	0	29	111	7.62	6.49	6.00	0	34	104
80	5.69	6.09	3.63	0	32	112	7.08	7.25	5.00	0	30.	98
96	6.39	6.04	5.00	0	28	107	7.07	7.33	5.00	0	36	98
Bech Rafaelsen Mania Rating Scale (MAS)												
0	1.84	2.40	1.00	0	13	152	2.38	2.84	1.00	0	13	145
16	2.14	3.08	1.00	0	15	131	2.16	3.25	1.00	0	17	123
32	1.80	2.82	1.00	0	18	122	1.80	2.61	1.00	0	14	119
48	1.21	2.12	0.00	0	11	117	2.17	3.50	1.00	0	20	111
64	1.83	2.77	1.00	0	15	111	2.03	3.39	1.00	0	18	104
80	1.84	3.02	1.00	0	16	112	1.33	1.84	1.00	0	11	98
96	1.88	3.53	1.00	0	18	107	1.84	4.14	0.00	0	30	98

Table A5. Self-rated secondary outcome measures: psychoeducation versus peer support groups in bipolar disorder.

Time point	**Psychoeducation (*n* = 153)**						**Peer Support (*n* = 151)**					
	M	SD	Med	Min	Max	*n*	M	SD	Med	Min	Max	*n*
Hospital Anxiety and Depression Scale (HADS) - Anxiety												
0	9.63	4.93	9.50	0.00	21.00	130	9.70	4.86	10.00	0.00	20.00	125
32	9.20	5.10	9.00	1.00	20.00	66	10.35	4.57	10.00	0.00	20.00	75
64	9.38	5.41	10.00	0.00	21.00	66	10.75	4.95	11.00	0.00	20.00	60
96	9.67	4.84	9.00	1.00	18.00	51	9.21	5.14	8.08	0.00	21.00	52
Hospital Anxiety and Depression Scale (HADS) - Depression												
0	8.24	4.78	8.00	0.00	19.00	130	8.22	5.29	8.00	0.00	21.00	125
32	7.12	4.92	7.00	0.00	21.00	66	8.37	4.81	8.00	0.00	19.00	75
64	6.98	5.13	6.50	0.00	20.00	66	8.85	4.98	9.00	0.00	21.00	60
96	7.46	5.68	6.00	0.00	21.00	51	7.58	5.40	7.00	0.00	19.00	52
Short-Form 12 (SF-12) - Mental Component Score												
0	37.0	12.1	34.8	13.6	63.2	128	36.1	12.1	33.4	12.8	63.7	120
32	37.5	11.7	37.6	15.3	62.8	66	36.6	10.9	34.0	14.1	57.3	75
64	37.9	13.2	35.4	13.0	66.7	66	35.0	11.1	33.5	16.1	61.0	60
96	38.9	12.8	36.6	12.1	60.3	49	37.1	11.4	34.1	19.2	60.6	52
Short-Form 12 (SF-12) – Physical Component Score												
0	43.8	11.0	43.8	17.6	63.4	128	46.1	11.5	47.2	18.6	65.9	120
32	43.1	12.3	43.6	18.0	62.7	66	43.0	12.3	44.8	15.8	64.5	75
64	43.4	11.6	44.8	15.5	62.1	66	42.0	12.0	42.6	13.3	64.4	60
96	44.2	12.3	44.4	16.8	62.0	49	42.1	11.5	40.8	21.8	63.8	52

Table A6. Interview functional secondary outcome measures: psychoeducation versus peer support groups in bipolar disorder..

	Psychoeducation (*n* = 153)						Peer support (*n* = 151)					
Time point	M	SD	Med	Min	Max	*n*	M	SD	Med	Min	Max	*n*
Social and Occupational Functioning Assessment Scale (SOFAS)												
0	75.8	12.2	80	40	91	143	76.5	12.3	80	41	91	137
32	72.5	13.2	71	41	94	121	71.9	13.1	71	21	94	113
64	74.1	14.3	80	11	91	110	74.0	12.3	80	40	95	99
96	75.4	13.5	80	41	100	106	73.1	14.5	72	32	95	96
Social Adjustment Scale (SAS) - Overall												
0	1.92	0.55	1.83	1.00	4.25	146	1.94	0.53	1.83	1.00	3.86	139
32	2.00	0.66	1.86	1.08	3.86	121	1.98	0.52	1.86	1.14	3.45	114
64	1.97	0.74	1.80	1.00	5.00	109	2.05	0.55	2.00	1.10	3.67	102
96	1.91	0.63	1.83	1.00	4.14	104	2.09	0.73	2.00	1.11	4.71	96
Social Adjustment Scale (SAS) - Performance												
0	2.23	0.80	2.00	1.00	5.00	146	2.31	0.82	2.17	1.00	5.00	139
32	2.36	0.85	2.33	1.00	5.00	121	2.38	0.89	2.15	1.00	4.50	114
64	2.30	0.88	2.14	1.00	5.00	109	2.37	0.83	2.27	1.00	5.00	102
96	2.31	0.94	2.15	1.00	5.00	104	2.42	0.96	2.21	1.00	5.00	96
Social Adjustment Scale (SAS) - Interpersonal												
0	1.70	0.60	1.62	1.00	3.67	146	1.77	0.58	1.67	1.00	3.33	139
32	1.81	0.70	1.67	1.00	5.00	121	1.73	0.69	1.67	1.00	4.00	114
64	1.64	0.61	1.50	1.00	4.67	109	1.73	0.63	1.57	1.00	3.33	102
96	1.52	0.55	1.33	1.00	3.67	104	1.75	0.76	1.43	1.00	5.00	96
Social Adjustment Scale (SAS) - Friction												
0	1.51	0.59	1.33	1.00	4.00	146	1.54	0.54	1.50	1.00	3.50	139
32	1.59	0.72	1.33	1.00	4.00	121	1.57	0.61	1.33	1.00	3.50	114
64	1.56	0.78	1.33	1.00	5.00	109	1.61	0.58	1.50	1.00	3.00	102
96	1.50	0.67	1.25	1.00	5.00	104	1.70	0.75	1.50	1.00	4.50	96
Social Adjustment Scale (SAS) - Dependency												
0	1.86	0.92	1.75	1.00	5.00	146	2.05	1.08	2.00	1.00	5.00	138
32	2.07	1.12	2.00	1.00	5.00	120	2.03	1.25	1.75	1.00	5.00	112
64	1.80	0.98	1.50	1.00	5.00	107	2.04	1.17	1.50	1.00	5.00	102
96	1.49	0.62	1.00	1.00	4.00	103	1.62	0.74	1.50	1.00	5.00	95

Table A7. Service user characteristics in qualitative study in group psychoeducation (PEd) and group support (PS) in bipolar disorder.

ID number	Group intervention	No. sessions attended	Age (Yrs)	Sex	Relationship status	Work status	No. episodes
SU001	PEd	15	29	F	Single	Employed	8-19
SU002	PEd	13	47	F	Divorced/Separated	Unemployed	1-7
SU003	PEd	14	49	F	Married/co-habiting	Unemployed	20+
SU004	PEd	19	59	M	Single	Unemployed	1-7
SU005	PEd	18	42	F	Married/co-habiting	Unemployed	20+
SU006	PEd	20	48	M	Single	Unemployed	8-19
SU007	PS	0 - drop out	42	F	Divorced/Separated	Employed	1-7
SU051	PEd	20	63	M	Married/co-habiting	Unemployed	20+
SU052	PEd	19	33	F	Married/co-habiting	Employed	1-7
SU053	PEd	20	59	M	Married/co-habiting	Unemployed	20+
SU054	PEd	19	57	M	Single	Unemployed	8-19
SU055	PEd	21	60	M	Married/co-habiting	Unemployed	20+
SU056	PEd	21	64	F	Married/co-habiting	Unemployed	20+
SU057	PEd	7 - drop out	58	M	Divorced/Separated	Unemployed	8-19
SU058	PEd	19	38	F	Single	Unemployed	8-19
SU059	PEd	1	55	M	Married/co-habiting	Unemployed	20+
SU060	PEd	2 - drop out	59	F	Divorced/Separated	Unemployed	20+
SU061	PEd	21	44	F	Married/co-habiting	Employed	20+
SU062	PEd	18	47	M	Divorced/Separated	Unemployed	20+
SU101	PS	19	60	M	Divorced/Separated	Unemployed	8-19
SU102	PS	18	30	F	Single	Unemployed	1-7
SU103	PS	15	26	F	Single	Unemployed	8-19
SU104	PS	17	54	F	Married/co-habiting	Unemployed	8-19
SU105	PS	14	29	M	Single	Unemployed	20+
SU106	PS	17	43	M	Single	Unemployed	20+
SU107	PS	17	67	M	Married/co-habiting	Unemployed	8-19
SU108	PEd	12	69	M	Divorced/Separated	Unemployed	8-19
SU109	PS	3 - drop out	48	F	Married/co-habiting	Unemployed	20+
SU151	PS	19	48	F	Divorced/Separated	Unemployed	20+
SU152	PS	11	52	M	Married/co-habiting	Unemployed	20+
SU153	PS	4 - drop out	36	F	Single	Unemployed	20+
SU154	PS	18	47	M	Divorced/Separated	Employed	8-19
SU155	PS	3 - drop out	48	M	Divorced/Separated	Employed	20+
SU156	PS	19	44	M	Married/co-habiting	Unemployed	20+
SU157	PS	18	50	F	Divorced/Separated	Unemployed	1-7
SU158	PS	8	33	F	Single	Unemployed	8-19
SU159	PS	19	66	M	Divorced/Separated	Unemployed	20+

PEd = group psychoeducation, PS = Peer support, M = male, F = female,

Table A8. Themes from qualitative study in group psychoeducation (PEd) and group support (PS)

1. Knowledge is power

Participants described having gained greater understanding about bipolar disorder (BD), the different forms it could take and ways of managing it, both in general, but also and how it applied to themselves. Participants felt this was an important outcome in its own right and that accessing information was a common reason for taking part in the trial. In particular, participants described how useful it had been to learn how the condition can affect them and their day-to-day living. Spending time reflecting back on previous events (particularly, for the PE group, the activity of charting their lifeline) helped them to understand their condition in different and more helpful ways.

'On holidays in the past I've had to come home because I've been so bad. This is way before the study. And now I can go away and think well if anything happens I can work on it, rather than get scared and just sort of abandon ship, and come to my home and curl up in bed… I have a little card which is in my hand written about the early warning signs and strategies, just in my wallet, so I take that with me every day everywhere I go and it's not there to show off its, well no-body see's it do they, well actually I have shown it to quite a few people and it's a constant reminder to me.' (SU053 PEd)

'*We learnt probably the same if not more of what they were just teaching just from our experiences from the other people with their experience of the mental health sector and erm... using the services and also just their own personal experience how they get out of scrapes and how they, how they bring themselves out of depression or stuff.'* (SU102 PS)

However, some participants commented that PS groups could feel unstructured and lack focus, which meant they were more vulnerable to dominant group members.

'I mean by the 5th week there was only about 5 or 6 of us left, so probably out of that group, probably only 1 or 2 you know that, erm… there was a couple of other people that I really wanted to listen to and I couldn't because this other person took the whole hour-and-a-half up and I suppose that upset me' (SU153 PS)

2. People like me

Participants described having often felt isolated. Having BD had impacted on their relationships and ability to work and often people felt unable to share experiences and thoughts about their condition with friends, family and work colleagues. Many described having withdrawn as a way of coping or having lost confidence in social interaction. Together, this had led some to become increasingly removed from other people. Many did not have regular contact with other people with BD, and meeting others who had similar experiences was raised as an important reason to take part and stay involved in the trial. Being able to associate with a group and share experiences with people they knew would understand was seen as comforting.

> *'You feel very lonely when you go through this sort of experience, so if, you know, there is other people, you know, that have had bad times like yourself it helps to give you a bit of relief that you are not on your own'* (SU004, PE)

Participants described feeling inspired by these encounters. In particular, meeting others who were able to function well and had recovered from severe episodes was encouraging, particularly amongst individuals who were more recently diagnosed.

'I found that quite inspiring to know there were people who had been sectioned, had been full blown woooo, and now have recovered to the degree that they can hold down some sort of work' (SU001, PEd)

Figure 1a. Recruitment by site and wave (n=304) in group psychoeducation (PEd) and group support (PS) for bipolar disorder.

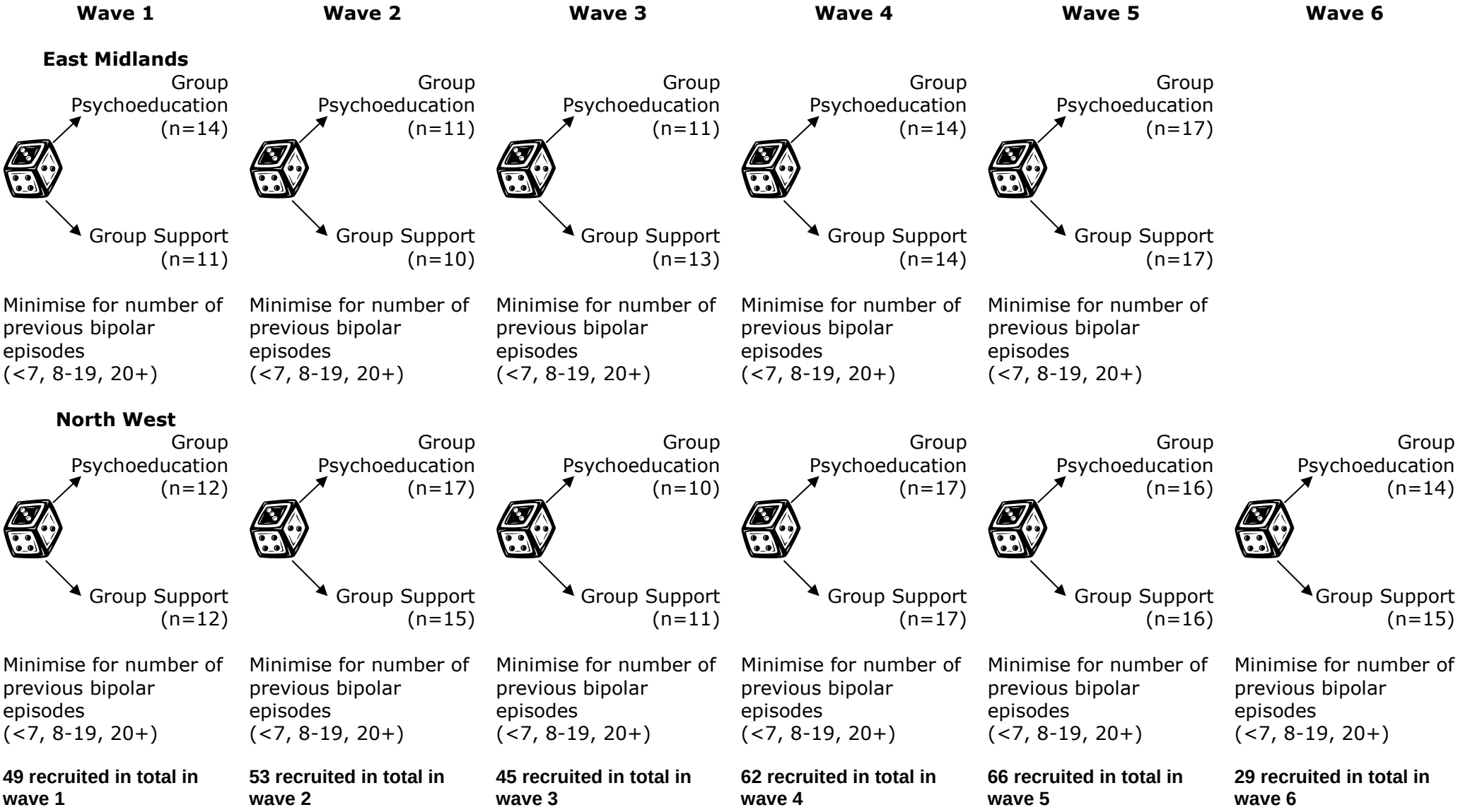

Figure 2a. Kaplan-Meier estimates of time to first mania-type or depressive bipolar episode by group and number of previous bipolar episodes in group psychoeducation (PEd) and group support (PS).