

Quality of Life of Participants with Bipolar and Schizoaffective Disorder in an Australian Cohort: Results After 12 Months

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BACKGROUND

Bipolar I Disorder

- Affects ~1% of the general population¹
- Mood disorder characterised by:
 - Acute, affective episodes (manic, depressed, mixed)
 - Full or partial inter-episode remission
 - Symptoms of psychosis, if present, occur during mood episodes only²
- Debilitating, long-term, recurrent condition with significant personal, social, and societal costs^{3,4}

Schizoaffective Disorder

- Similar prevalence and features as bipolar disorder¹
- Characterised by both mood episodes and features of psychosis e.g. hallucinations, delusions, disturbed thinking²
- Symptoms of psychosis occur during or separate from the mood disturbance²

1. Weissman MM, et al. JAMA. 1996;276(4):293-299.

2. DSM-IV-TR. (2000). American Psychiatric Association.

3. Bauer MS, et al. J Affect Disord. 2001;65:231-241.

4. Goldberg JF, et al. J Affect Disord. 2005;89(1-3):79-89.

BCOS

The **B**ipolar **C**omprehensive **O**utcomes **S**tudy

- BCOS is examining outcomes associated with treatment in a “**real-life**” context.
- The primary objective of the study is to compare the proportion of patients with bipolar I or schizoaffective disorder that experience symptomatic relapse following treatment with olanzapine as a mood stabiliser versus conventional mood stabilisers, which will be reported elsewhere.
- Secondary objectives include the further assessment of clinical, functional, quality of life, and economic outcomes.
- **Here we report on the quality of life outcomes for participants after 12 months observation.**

METHODOLOGY

STUDY DESIGN

- Two-year, prospective, observational, open-label study
- Two study centres in Victoria, Australia
- Usual standard-of-care at the discretion of the treating team and no concomitant medication was excluded
- Participants prescribed at least one of the following at baseline:
 - **Olanzapine** – **Lithium carbonate**
 - **Sodium valproate** – **Carbamazepine**
- Study assessments at baseline and every 3 months
- Assessment of adverse events (incl. weight change) were conducted as part of participants’ normal clinical management and any consequent changes to medication/dosage were at the discretion of the investigator.

QUALITY OF LIFE MEASURES

- EuroQol Instrument – Five Dimensions (EQ-5D):
 - Self-rated scale assessing overall health status.
- Visual Analogue Scale (VAS):
 - Self-rated scale assessing overall health status.
- 36-item Short Form Health Survey (SF-36):
 - Self-rated scale assessing generic QoL including assessment of mental & physical functioning and well-being.
- Streamlined Longitudinal Interview Clinical Evaluation from the Longitudinal Interval Follow-up Evaluation (SLICE/LIFE):
 - Disease-specific scale assessing life satisfaction, relationships, and work status.
- Diagnostic Interview for Psychosis (DIP):
 - Structured interview assessing work status, attendance, unmet needs and service usage.

DATA ANALYSIS

- Study Entry comparisons were assessed using Fisher's Exact Test for categorical measures and ANOVA or the medians test for continuous measures.
- All longitudinal profiles were assessed using Mixed Model Repeated Measures (MMRM*) adjusted for the following:
 - Study entry factors: Age, gender, diagnosis, length of hospital stay in previous 3 months, hospitalised, overall CGI-BP-S, alcohol dependence past 12 months (from MINI), smoking status, partner status, employment status, visit and site.
 - Medications taken over the 12 months: amount of time on Mood Stabilizers and/or Antidepressants and/or Antipsychotics and/or Benzodiazepines/Hypnotics.
- Interaction effects were assessed at the 0.1 level.

* MMRM with random effect for time & intercept. Model statement includes visit & visit². Covariance Structure used was Spatial Power.

DEMOGRAPHICS

Characteristics at Baseline (N=239)	Overall
Age, years (range)	41.8, 18 to 79
Women	58%
Bipolar I disorder	73%
Smoked Daily	51%
Consumed alcohol 3+ days/week (3 months pre-enrolment):	26%
Unemployed	29%
Prevented from working by mental illness	18%
Rating of Life Satisfaction (3 months pre-enrolment):	
Satisfied/Very Satisfied	47%
Dissatisfied/Very Dissatisfied	30%
Currently in a romantic relationship	41%
At least 1 day in hospital (3 months pre-enrolment)	33%

Reasons for Drop-Out

- After 12 months, 7 participants had decided to discontinue from the study.
- Two participants died due to medical causes.

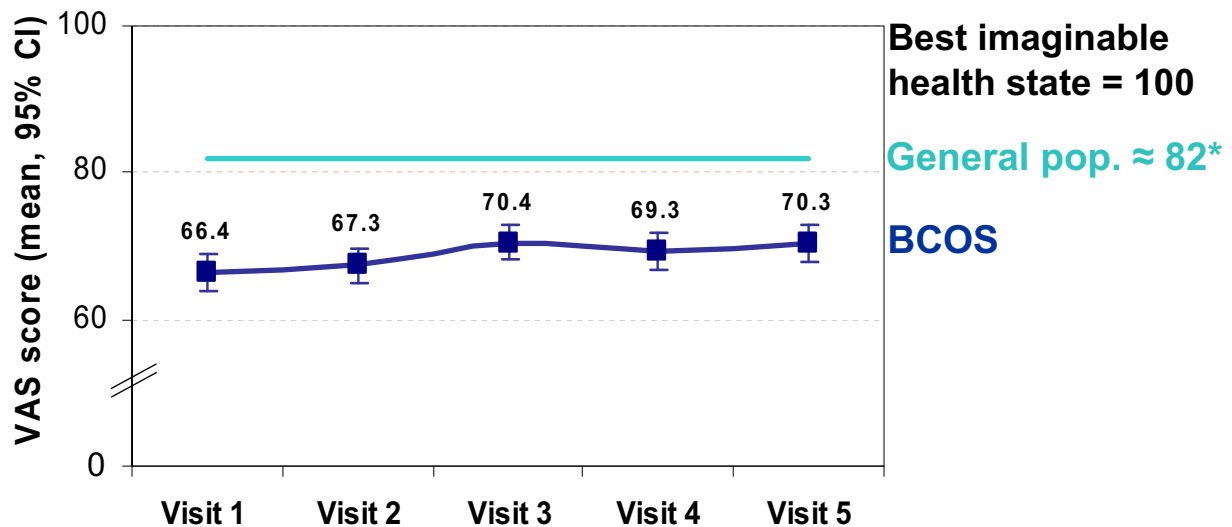
Participant Disposition	Total (N = 239)	
	n	%
Completed*	175	73.2
Partially completed	50	20.9
Participant decision	7	1.9
Lost-to-follow-up	4	1.7
Death**	3	1.3

*Total number entered into database at 12 month data lock

**2 medical cause, 1 suicide

EQ-5D VAS: Overall Health State

- Self-rated overall health significantly improved over 12 months ($p=.005$).

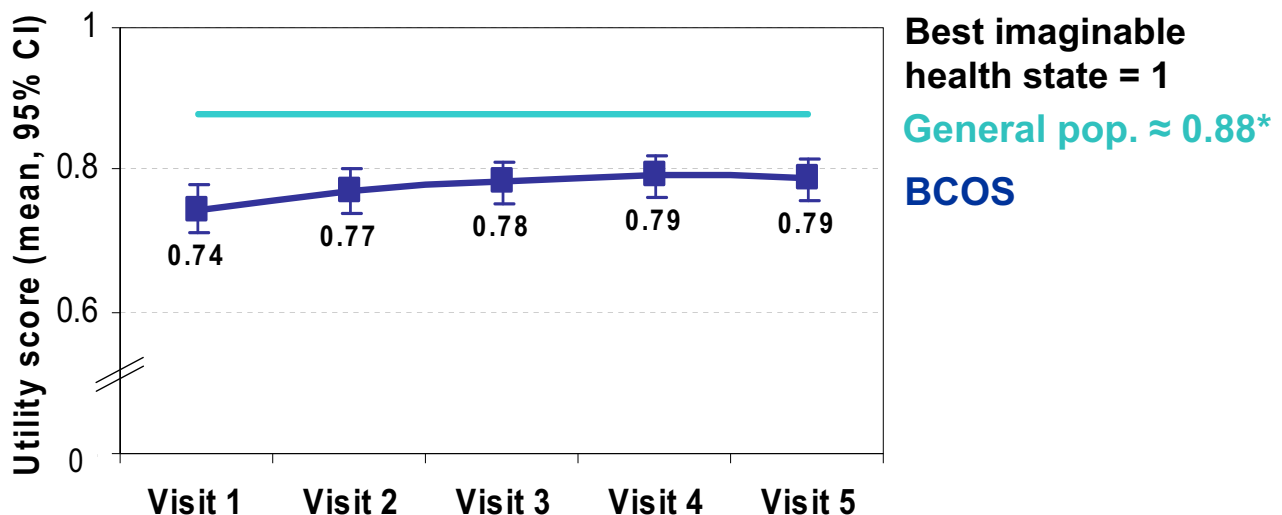


* Koltowska-Hägström et al. (2005). *Horm Res* 64: 46-54.

Baseline: N = 239
12 months: N = 220

EQ-5D: Utility scores

- EQ-5D utility scores significantly increased over 12 months ($p=.095$).
- 67% of patients 'Low' on EuroQoL - Normal Indicator (age/sex adjusted).

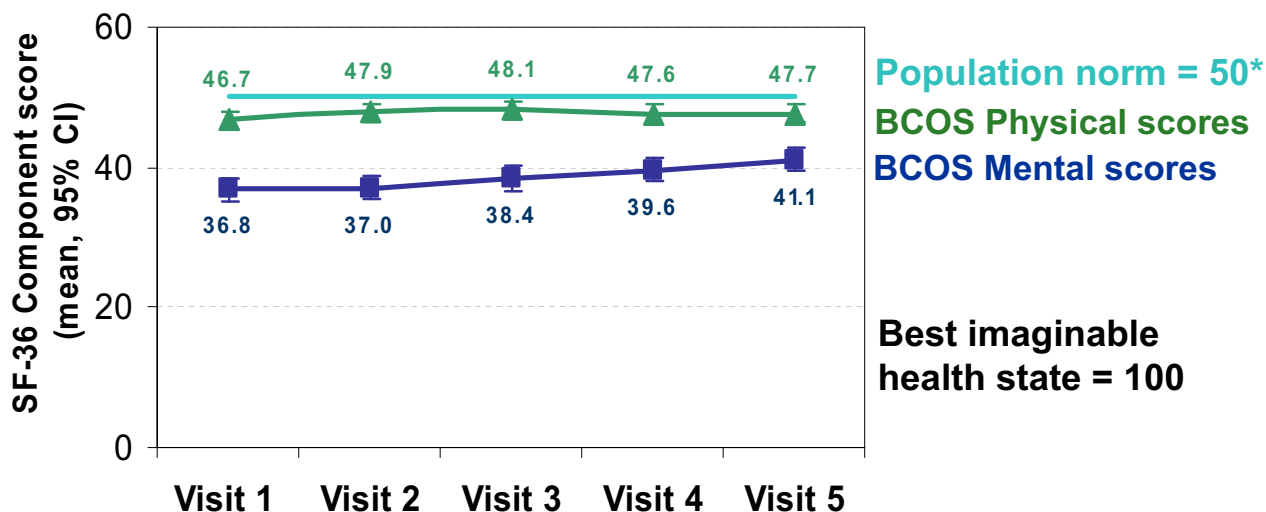


* Australians aged 36-50 years, Hawthorne et al. (2001). *Ann Med* 33: 358-370.

Baseline: N = 239
12 months: N = 220

SF-36: Mental & Physical Health

- Standardised **mental** ($p < .001$) and **physical** ($p = .047$) component scores significantly increased over 12 months.

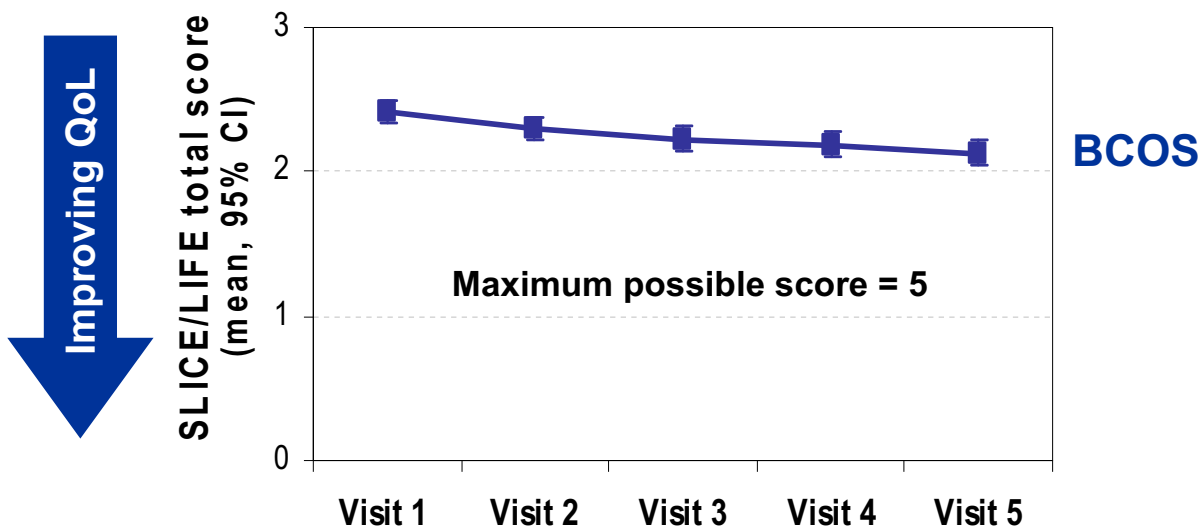


* Ware & Sherbourne (1992). *Medical Care* 30: 473-483.

Baseline: N = 236
12 months: N = 221

QUALITY OF LIFE

- Self-reported quality of life significantly improved over 12 months ($p < .001$), as measured by **SLICE/LIFE** total scores.

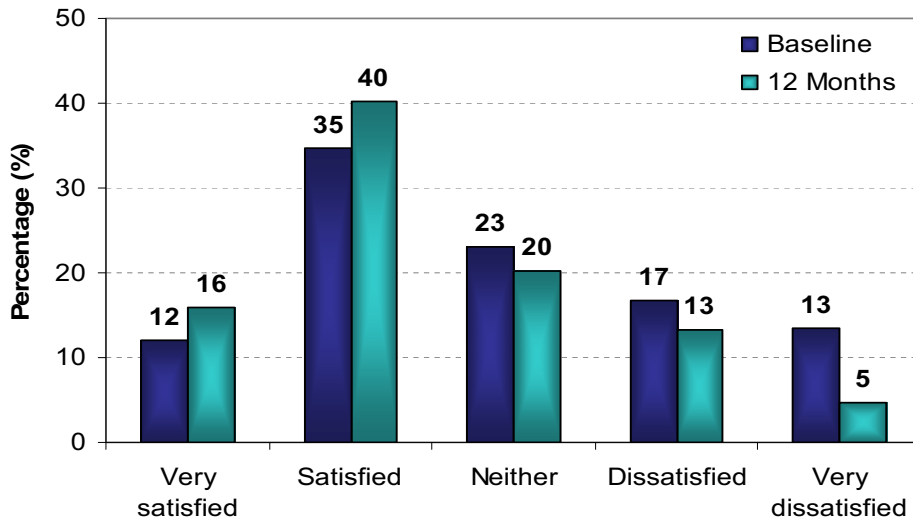


Baseline: N = 239
12 months: N = 220

LIFE SATISFACTION

SLICE/LIFE: Rating of life satisfaction

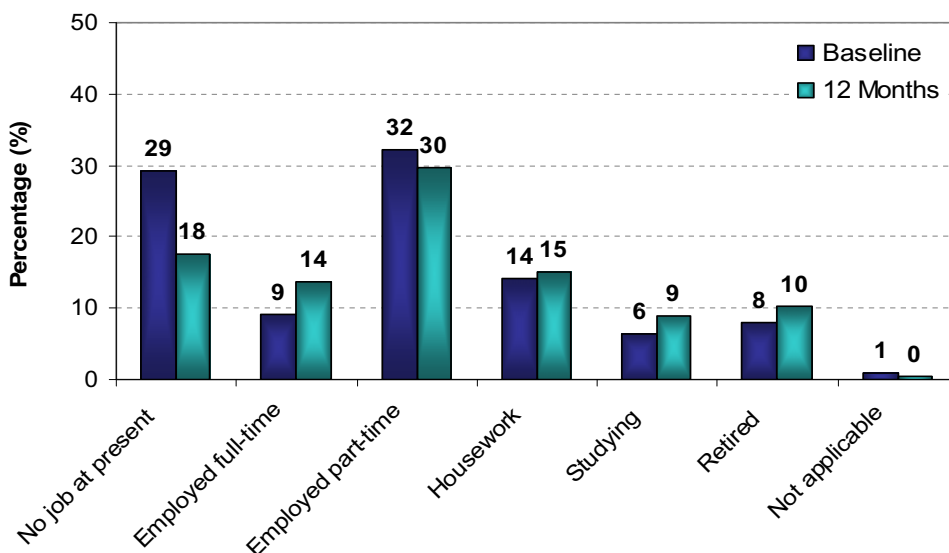
- More participants were satisfied or very satisfied with their overall health after 12 months: 56% vs. 47% at baseline.



Baseline: N = 239
12 months: N = 233

EMPLOYMENT STATUS

- 90% of participants with employment at baseline were still employed after 12 months, with unemployment also decreasing during this time.
- Unemployment remained higher than Australia-wide rate: 5.1%.*

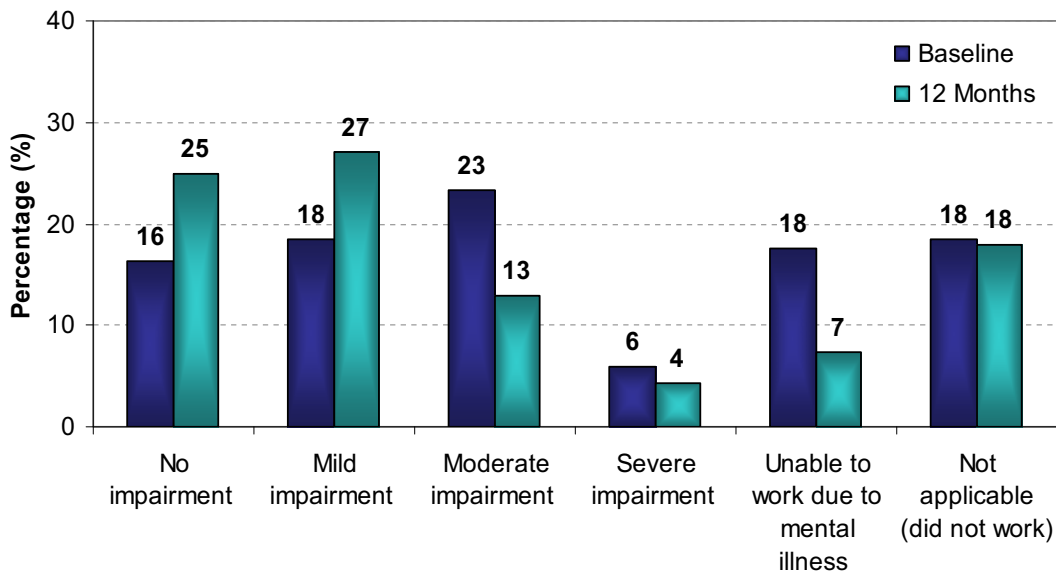


* Australian Bureau of Statistics (2005)

Baseline: N = 239
12 months: N = 233

WORK IMPAIRMENT

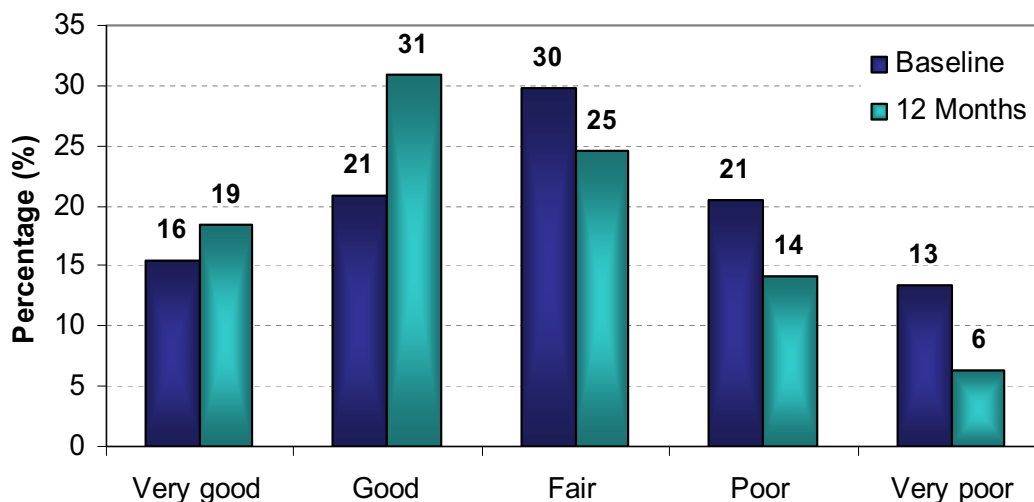
- After 12 months:
 - Mental illness prevented fewer participants from working.
 - Overall severity of work impairment was reduced.



Baseline: N = 239
12 months: N = 233

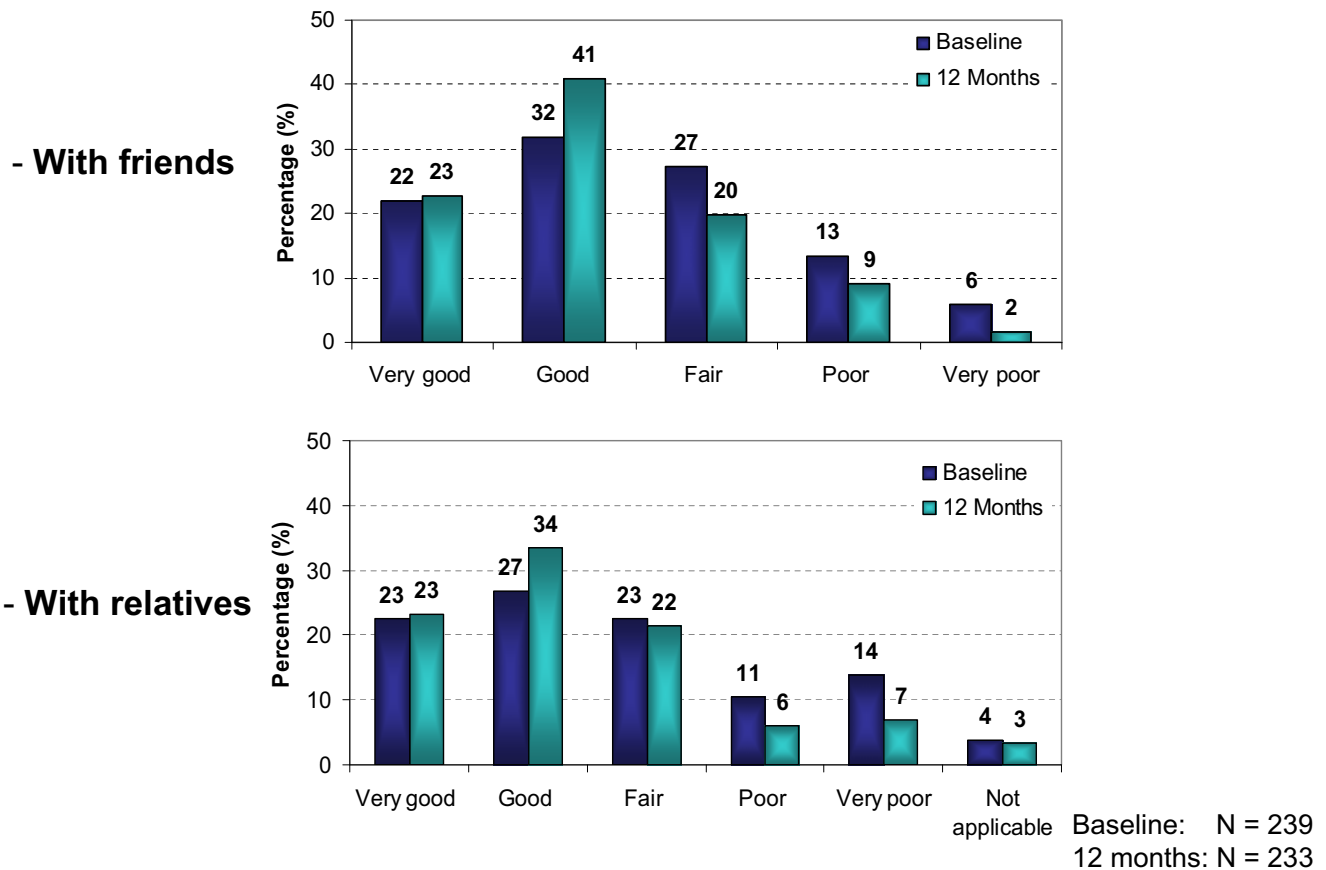
SOCIAL FUNCTIONING

- After 12 months:
 - **Overall improvement in social functioning**
 - Self-reported improved enjoyment of **recreational activities**:



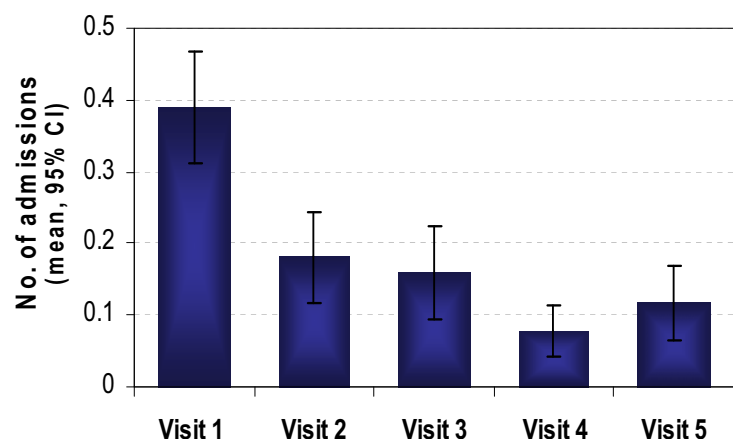
Baseline: N = 239
12 months: N = 233

Self-reported improvement in relationships:



HOSPITALISATION

- 28% of participants were hospitalised at least once.
- Significantly fewer illness-related hospital admissions after 12 months ($p < .001$).
- No participants were in hospital for 12 month visit: 0% vs. 7% baseline.



12 month Summary	n	Mean (SD)	min	max
Length of stay (days)	238	8.9 (18.4)	0	93
Length of stay (non zero days)	79	26.8 (23.4)	1	93
No. of admissions	239	0.5 (1.1)	0	7

Summary of Results

Scale	Baseline ^a	12 months ^a	Overall ^b	P-value
EQ-5D Health State	66.4 (63.85 – 68.95)	70.3 (67.80 – 72.80)	68.9 (64.84 – 73.04)	.005
EQ-5D Utility	0.74 (0.71 – 0.78)	0.79 (0.76 – 0.82)	0.78 (0.73 – 0.84)	.095^c
SF-36 Mental	36.8 (35.17 – 38.46)	41.1 (39.43 – 42.75)	37.3 (34.45 – 40.21)	<.001
SF-36 Physical	46.7 (45.39 – 49.85)	47.7 (46.33 – 49.04)	48.23 (45.95 – 50.51)	.047^c
SLICE/LIFE Total	2.42 (2.33 – 2.50)	2.13 (2.05 – 2.21)	2.30 (2.15 – 2.45)	<.001
SLICE/LIFE Work	2.55 (2.40 – 2.69)	2.07 (1.93 – 2.20)	2.34 (2.10 – 2.59)	<.001
SLICE/LIFE Interpersonal	2.59 (2.44 – 2.74)	2.37 (2.18 – 2.64)	2.41 (2.18 – 2.64)	.008^c

^a Values are observed means (95% CI),

^b Values are means (95% CI), adjusted for age, gender, diagnosis, no. of alcoholic drinks per day and smoking.

^c Visit*Visit analysis. Significance level set at $p < .10$.

CONCLUSIONS

- People with bipolar and schizoaffective disorders experience diminished quality of life.
- After 12 months observation, BCOS study participants have improved on many QoL measures.
- Emerging patterns can be further explored with QoL assessments at the 24 month study endpoint.
- The results of BCOS will enhance understanding of real-life clinical practice outcomes of patients receiving pharmacological treatment for bipolar and schizoaffective disorders in Australia.

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