

Development, Psychometric Validation and User Centred Evaluation of a Patient Information Leaflet for Bipolar Disorder: A Quasi-experimental Study

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ABSTRACT

Introduction: Bipolar Disorder (BD) is a complex psychiatric mood disorder. Despite its complexity, nearly half of the patients experience medication non adherence due to poor insight into the illness. Therefore, improving patient knowledge using a Patient Information Leaflet (PIL) regarding the disease and its treatment is crucial.

Aim: To develop and validate a PIL and to assess knowledge levels among patients with BD.

Materials and Methods: A prospective quasi-experimental study was conducted from June 2025 to November 2025 at Justice KS Hegde Charitable Hospital (JKSHCH), Dakshina Kannada, India. A total of 42 patients with BD aged 18 years or older were included. Demographic details, including age, gender, education, and domiciliary status were collected for analysis. The PIL was developed using information from relevant literature and translated into regional languages. Content validity was assessed using the Content Validity Index (CVI). Readability was evaluated using the Flesch Reading Ease (FRE) and Flesch-Kincaid Grade Level (FKGL) formulas. The design quality was

assessed using the Baker-Able Leaflet Design (BALD) criteria. The reliability of the Patient Knowledge Questionnaire (PKQ) was determined using the Intraclass Correlation Coefficient (ICC). A paired t-test was performed using Statistical Package for the Social Sciences (SPSS) version 29.0 to compare knowledge levels before and after reading the PIL. A p-value<0.05 was considered as statistically significant.

Results: The PIL achieved CVI scores of 0.93 for relevance and 0.91 for clarity, indicating excellent content validity. Readability scores of 83.3 (FRE) and 2.8 (FKGL) suggest that the leaflet can be easily understood by individuals with education beyond grade three. BALD scores were 28 in English and 26 each in Kannada and Malayalam, indicating good leaflet design. ICC values ranged from 0.6 to 1 across questionnaire versions, demonstrating high reliability. The post-test results results showed a significant improvement in patient knowledge after reading the PIL.

Conclusion: The systematically developed and validated PIL effectively improves patients' understanding of BD and its treatment, which may enhance medication adherence and quality of life.

Keywords: Patient education material, Psychiatric disorder, Readability, Reliability

INTRODUCTION

Bipolar Disorder (BD) is one of the most common psychiatric disorders worldwide. It is a multifactorial and complex illness that typically begins in early adulthood and persists throughout life, characterised by recurrent mood alterations [1]. Approximately seven billion people are affected globally, with an estimated prevalence of 2.4% and a biannual relapse rate of 54.3% [2,3]. In many cases, BD is complicated by the presence of co-morbid psychiatric and medical conditions [4]. Owing to its complexity, patients often require treatment with multiple psychotropic medications [5].

Mood stabilisers and anticonvulsants form the cornerstone of BD management [6]. Among these, lithium remains one of the most widely used agents and often requires lifelong therapy with regular follow-up to prevent relapse. However, long-term lithium use may negatively influence medication adherence [7]. Studies report that nearly 50% of outpatients with BD do not take their medications consistently, largely due to adverse effects and poor insight into the illness [8]. Abrupt discontinuation may result in treatment failure, withdrawal symptoms, and frequent relapses. Therefore, educating patients and caregivers about the disease and its treatment is essential and can be facilitated through structured educational materials [9].

Patient education using information leaflets is considered an essential component of chronic disease management [10]. PILs are simple,

cost-effective tools that provide validated and standardised information regarding diseases, medications, and lifestyle modifications [11]. However, the readability and quality of many PILs are seldom assessed prior to use [12]. Previous studies indicate that evaluating these aspects improves patient comprehension and engagement [13,14]. Hence, the present study aimed to systematically develop, validate, and assess a PIL and to evaluate its impact on knowledge levels among patients with BD, addressing a gap in existing literature.

MATERIALS AND METHODS

This prospective quasi-experimental study was conducted from June 2025 to November 2025 in the Department of Psychiatry at Justice KS Hegde Charitable Hospital (JKSHCH), Mangaluru, Karnataka, India. Institutional Ethical Clearance (IEC Ref. No. NGSIMPS/IEC/026/2025) was obtained prior to study initiation. Written informed consent was obtained from all participants.

Inclusion criteria: Patients aged 18 years or older diagnosed with BD who could read and understand at least one of the following languages-Kannada, Malayalam, or English-were included in the study.

Exclusion criteria: Patients undergoing treatment for chronic co-morbid conditions were excluded from the study.

Demographic data, including age, gender, education level, and domiciliary status were collected using a structured data collection form.

Sample size calculation: The sample size was calculated based on a previous study by Poojari PG et al., in which the post-test standard deviation scores for knowledge assessment was reported as 11.54 [15]. With an absolute precision of 3.5 and a 95% confidence interval, the required sample size was determined to be 42 participants, with 14 patients in each language group (English, Kannada, and Malayalam).

The sample size was calculated using the following formula:

$$n = \frac{Z^2 \frac{\sigma^2}{d^2}}{\alpha/2}$$

$Z^2\alpha/2 = 1.96$ (at 5% level of significance)

σ = Standard deviation.

d = Margin of error.

where, CI=95%, $Z^2\alpha/2=1.96$, standard deviation (σ)=11.54, margin of error (d)=3.5

Study Procedure

Preparing and revising the content of the PIL: Various literature sources were used to develop the content of the PIL. These included primary resources (PubMed and Scopus-indexed journals), secondary resources (Medscape and UpToDate), and tertiary resources (textbooks such as Pharmacotherapy: A Pathophysiologic Approach [16] and Harrison's Manual of Medicine [17]). In addition, recommendations and suggestions from experienced psychiatrists were incorporated. The PIL content covered disease definition, signs and symptoms, medication benefits and side-effects, lifestyle modifications, and dietary recommendations. Visual representations were also included to enhance patient comprehension.

Content Validation of the PIL

The Content Validity Index (CVI) method was applied to validate the PIL. A 13-member expert panel was formed, comprising five psychiatrists, one clinical psychologist, one dietitian, three academic pharmacists, one clinical pharmacist, one senior researcher from the Department of Science and Technology (DST), and one social worker. All experts had a minimum of five years of clinical or teaching experience in their respective fields.

The initial draft of the PIL was provided to each expert along with a content validation form. Experts were requested to review and score each item. For precise assessment, the content was divided into the following items:

- Item 1: Definition of BD
- Item 2: Manic episodes
- Item 3: Depressive episodes
- Item 4: Medications and prevention
- Item 5: Possible medication side-effects
- Item 6: Self-care tips
- Item 7: Healthy and unhealthy foods
- Item 8: Physical activity and duration

Experts were also encouraged to provide suggestions and recommendations.

The content validation form used a four-point Likert scale for relevance and clarity [18]:

- 1=Not relevant / Not clear
- 2=Needs major revision
- 3=Needs minor revision
- 4=Very relevant / Very clear

Scores were recoded into two categories: 1 (scores of 3 or 4) and 0 (scores of 1 or 2). The Item Content Validity Index (I-CVI) was calculated for each item, while the Scale Content Validity Index (S-CVI) was computed as the average of all I-CVI values. An S-CVI value ≥ 0.8 indicated excellent content validity. Items scoring between 0.6 and 0.7 required revision, whereas items below 0.6 were eliminated [19].

Cohen's Kappa Coefficient of the PIL

Cohen's Kappa coefficient (κ) was used to assess inter-rater agreement and reliability of the PIL. Although CVI is widely used for content validation, it does not account for agreement occurring by chance, which may bias results. Chance agreement may arise when the four-point ordinal scale is dichotomised into two categories (1 or 0) during analysis. Therefore, Cohen's Kappa provides a more robust measure of agreement beyond chance and serves as an important complement to the CVI method [20].

The following formula was applied to determine the probability of chance agreement (P_c) for each item:

$$P_c = \left[\frac{N}{A(N-A)} \right] \times 0.5N$$

where (P_c)=Probability of chance agreement

N = Total number of experts who agree on the relevance of the item

A = Number of experts who agree the item is relevant

The formula to calculate Cohen's Kappa coefficient (κ) is mentioned below:

$$\kappa = \frac{(1 - CVI - P_c)}{(1 - P_c)}$$

where (P_c)=Probability of chance agreement

I-CVI=Item content validity index

According to Cohen's Kappa (κ) evaluation criteria, scores are categorised as excellent (>0.74), good (0.60-0.74), and fair (0.40-0.59) [18].

Readability Scores of the PIL

The two most commonly used methods to assess the readability of PILs are the FRE and FKGL formulas [21]. To determine these scores, the content of the PIL was entered into a Microsoft Word document, and the readability tool from Microsoft Word was used to generate FRE and FKGL values. The FRE score represents the simplicity of the content and ranges from 0 to 100. A score above 70 indicates that the leaflet is easy to read. The FKGL score assesses content complexity and ranges from 0 to 12, with higher scores indicating increased difficulty. An FKGL score of 8 or lower is considered acceptable for standard patient education materials [21].

Design and Layout Features

The quality of the PIL was evaluated using the BALD tool, which assesses four components: layout, design, content, and paper quality. Scores above 20 indicate good leaflet design and layout quality [22].

Validation and reliability of Patient Knowledge Questionnaires (PKQ)

Based on the PIL content (Supplementary 1) and discussions with experts, the PKQ was developed in three languages to assess patients' knowledge before and after receiving the PIL. The same 13-member expert committee validated the questionnaire to ensure content accuracy and clarity.

The 10-item PKQ (Supplementary 1) was translated into Kannada and Malayalam by certified language professionals with healthcare expertise. To assess reliability, a test-retest method was conducted in a pilot group of 21 BD patients. Each language version was administered to seven participants. One week later, the same questionnaire was re-administered to the same patients. The PKQ was considered reliable if similar scores were obtained during both assessments [23].

Knowledge Assessment of BD Patients

A total of 42 BD patients were randomly recruited and divided into three groups based on language preference, with 14 patients in each group. Each group received the PIL and PKQ in their respective language.

Initially, patients completed the PKQ as a baseline assessment. They were then allowed to read the PIL thoroughly for approximately 20 minutes. Afterward, the PKQ was re-administered to evaluate improvement in their knowledge levels [24].

Knowledge improvement was calculated using the following formula:

$$\text{Response evaluation} = \frac{\text{Total number of correct responses by the patient}}{\text{Total number of actual responses}} \times 100\%$$

STATISTICAL ANALYSIS

The Intraclass Correlation Coefficient (ICC) was used to assess PKQ reliability, with values ranging from 0 to 1. An ICC below 0.5 indicated poor reliability, 0.5-0.7 moderate reliability, and 0.8-0.9 good to excellent reliability [25]. Descriptive statistics were applied to analyse categorical variables. SPSS version 29.0 was used to perform paired t-tests to compare knowledge before and after providing the PIL. A p-value < 0.05 was considered statistically significant.

RESULTS

Among the BD patients, males (n=26; 61.9%) outnumbered females (n=16; 38.1%). The mean age of participants was 43.6±14.3 years. Most patients resided in rural areas (n=23; 54.8%). Clinically, the majority were diagnosed with BD with manic episodes (n=21; 50%), followed by BD with depressive episodes (n=12; 28.6%). Socio-demographic details are presented in [Table/Fig-1].

Content Validation of Leaflet

Following expert evaluation using the CVI method, most content items were deemed appropriate, with only one item requiring minor revision. Both I-CVI and S-CVI scores for relevance and clarity exceeded 0.8, indicating excellent content validity. Detailed validation results are shown in [Table/Fig-2].

Cohen's Kappa Coefficient

Cohen's Kappa analysis demonstrated perfect agreement for all PIL items ($\kappa=1$), indicating excellent inter-rater reliability without chance bias. Kappa values are presented in [Table/Fig-3].

Readability Scores

The FRE and FKGL scores of the PIL were 83.3 and 2.8, respectively, indicating that the content is easily understandable for individuals with education beyond grade three. Readability results are shown in [Table/Fig-4].

Design and Layout Features

BALD scores were 28 for the English version and 26 each for the Kannada and Malayalam versions, indicating well-designed and reader-friendly leaflets. Details are presented in [Table/Fig-5].

Characteristics	n (%) or mean±SD (n=42)
Age (mean±SD) (in years)	43.6±14.3
Age group distribution	
19-33	13 (30.95)
34-48	15 (35.7)
49-63	10 (23.8)
64-78	4 (9.52)
Gender	
Male	26 (61.9)
Female	16 (38.1)
Educational status	
Primary (1-10 th class)	9 (21.4)
Secondary (11-12 th class)	23 (54.8)

Graduate	6 (14.3)
Post graduation	4 (9.5)
Domiciliary status	
Rural	23 (54.8)
Urban	19 (45.2)
Diagnosis	
BD with manic symptoms	21 (50)
BD with depressive episodes	12 (28.6)
BD without manic symptoms	9 (21.4)

[Table/Fig-1]: Patients characteristics on sociodemographics.

Relevance rating on the tool by the experts (n=13)				Clarity rating on the tool by the experts (n=13)			
Item No.	Accepted	I-CVI	Inference	Item No.	Accepted	I-CVI	Inference
Item 1	9	0.69	Needs revision	Item 1	9	0.69	Needs revision
Item 2	12	0.92	Appropriate	Item 2	11	0.85	Appropriate
Item 3	13	1	Appropriate	Item 3	13	1	Appropriate
Item 4	13	1	Appropriate	Item 4	13	1	Appropriate
Item 5	11	0.85	Appropriate	Item 5	11	0.85	Appropriate
Item 6	13	1	Appropriate	Item 6	13	1	Appropriate
Item 7	13	1	Appropriate	Item 7	12	0.92	Appropriate
Item 8	13	1	Appropriate	Item 8	13	1	Appropriate
S-CVI/Ave=0.93				S-CVI/Ave= 0.91			

[Table/Fig-2]: Content validation of leaflet.

I-CVI: Item content validation index, S-CVI: Scale content validation index

Relevance rating on the tool by the experts				
Item No.	Experts in agreement	I-CVI	κ	Interpretation
Item 1	9	0.69	1	Excellent
Item 2	12	0.92	1	Excellent
Item 3	13	1	1	Excellent
Item 4	13	1	1	Excellent
Item 5	11	0.85	1	Excellent
Item 6	13	1	1	Excellent
Item 7	13	1	1	Excellent
Item 8	13	1	1	Excellent

[Table/Fig-3]: Cohen's Kappa coefficient.

I-CVI: Item content validation index, κ = Cohen's Kappa coefficient

Readability	Observed value
Flesch Reading Ease (FRE)	83.3
Flesch-Kincaid Grade Level (FKGL)	2.8

[Table/Fig-4]: Readability of the leaflet.

Reliability of Patient Knowledge Questionnaire (PKQ)

Test-retest analysis among 21 patients demonstrated ICC values ranging from 0.6 to 1 across all language versions, confirming moderate to excellent reliability. ICC results are provided in [Table/Fig-6].

Knowledge Assessment of BD Patients

Knowledge assessment among 42 patients revealed a significant increase in post-test scores after reading the PIL across all language groups. Detailed results are presented in [Table/Fig-7].

DISCUSSION

A leaflet is a practical, non pharmacological approach to promote improved therapeutic outcomes in patients with BD. The PIL provides information about the disorder, enabling patients and caregivers to better understand the condition and recognise early warning signs and mood changes. This understanding helps ensure optimal treatment adherence [26]. Numerous studies

Design characteristics	3 points	2 points	1 point	0 point	English	Kannada	Malayalam
Lines 50-89 mm long			Yes	No	1	1	1
Separation between lines	>2.8 mm	2.2-2.8 mm		<2.2 mm	3	3	3
Lines unjustified			Yes	No	1	1	1
Serif typeface		Yes		No	2	0	0
Type size	12 points	10-11 point	9 points	<9 points	3	3	3
First line indented			Yes	No	0	0	0
Titles lower case			Yes	No	1	1	1
Italics		0 words	0-3 words	≥4 words	2	0	0
Positive advice		Positive		Negative	2	2	2
Headings standout		Yes		No	2	2	2
Numbers all Arabic			Yes	No	0	0	0
Boxed text			0-1 box	>1 box	1	1	1
Pictures	Word count not replace	In between	In between	None or super flours	1	3	3
Number of colours	4	3	2	1	3	3	3
White space	>40%	30-39%	20-29%	<20%	3	3	3
Paper quality	>90 gsm	75-90 gsm		<75 gsm	3	3	3
Total					28	26	26

[Table/Fig-5]: Baker-Able Leaflet Design (BALD) scores.

Characteristics	Pretest	Post-test	ICC value
Kannada	49±11	51±11	0.878
Malayalam	46±7.8	46±5	0.667
English	47.1±12.5	47±12.5	1

[Table/Fig-6]: Reliability of Patient Knowledge Questionnaire (PKQ).

Characteristics	Pretest	Post-test	p-value
Kannada	54±8.9	77±7.95	<0.001
Malayalam	51±7.42	72.8±13.8	<0.001
English	47.8±12.51	72.8±9.13	<0.001

[Table/Fig-7]: Knowledge assessment of BD patients.

evaluating PILs in major psychiatric disorders such as depression, schizophrenia, and substance use disorders have demonstrated that high-quality educational materials improve patient knowledge, enhance patient-clinician interaction in treatment decisions, and contribute to faster symptom recovery [13,27,28]. However, only a limited number of studies have developed and assessed educational tools specifically for patients with BD [29]. Developing a comprehensive yet user-friendly leaflet that covers all aspects of BD is challenging. The inclusion of complex scientific terminology may confuse individuals with lower literacy levels [30]. Therefore, effective leaflet design requires multidisciplinary expert input [19]. A PIL can serve as a valuable source of information, especially in busy outpatient settings where clinicians may not have sufficient time to provide extensive verbal counselling [13,31]. Furthermore, patients and caregivers may not retain all verbal information provided during consultations [32].

The PIL developed in the present study underwent systematic quality assurance procedures. Initially, content was compiled from multiple literature sources and subsequently validated using the CVI method with expert committee support. The CVI scores obtained 0.93 for relevance and 0.91 for clarity—indicated excellent content validity [19], consistent with findings from prior studies on educational leaflets for diabetic foot ulcers [33]. To account for chance agreement among experts, Cohen's Kappa statistics were applied, yielding a value of 1, which reflects perfect reliability [18]. Providing PILs with pictorial representations enhances readability and comprehension [11]. The developed leaflet achieved an FRE score of 83.3, indicating easy readability. The FKGL score of 2.8 suggests that individuals with education beyond grade three can understand the content. Additionally, the BALD score of 28

confirmed high-quality design and layout, comparable to other validated educational tools for chronic diseases [34,35].

Regarding questionnaire reliability, the English version achieved an ICC value of 1, indicating perfect reliability. The Kannada and Malayalam versions yielded ICC values of 0.8 and 0.6, respectively, reflecting moderate to good reliability. Similar findings were reported by Gopinath DC et al., in schizophrenia patients, where ICC values of 1 for English and 0.68 for Kannada versions were observed [13]. Variations in ICC values may be influenced by patient demographic characteristics. The patient knowledge assessment in the present study demonstrated a substantial improvement in knowledge levels after using the PIL. These findings are consistent with a study by Poojari PG et al., which reported an increase in knowledge scores from 60.62±23.69 to 91.25±11.54 [15]. The combination of textual information and visual aids likely contributed to improved comprehension and retention.

Limitation(s)

The validation process relied on national experts; inclusion of international experts might have offered additional perspectives. Although patient knowledge improved significantly following PIL use, larger-scale studies involving broader BD populations are necessary to strengthen the generalisability of these findings.

CONCLUSION(S)

This study systematically developed and validated a PIL specifically for patients with BD. The results confirmed that the leaflet significantly improved patient knowledge. Enhanced understanding of the disease and its treatment may contribute to better medication adherence and improved quality of life.

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