

SCREENING AND EARLY MANAGEMENT OF DEPRESSION IN PRIMARY HEALTHCARE SETTINGS: A PROSPECTIVE OBSERVATIONAL STUDY

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ABSTRACT

Background: Depression is a leading cause of disability worldwide, yet it remains under-detected in primary healthcare (PHC) settings, particularly in low- and middle-income countries. Effective screening strategies can bridge this gap, but evidence from Indian PHC contexts is limited. The objective is to evaluate the impact of systematic depression screening on identification rates and early management outcomes among adults attending a primary care clinic. **Materials and Methods:** This prospective observational study was conducted at Kumaran Hospital, Coimbatore, from April 2024 to April 2025. A total of 162 adults aged 25–60 years were consecutively enrolled. All participants underwent systematic screening using the Patient Health Questionnaire-9 (PHQ-9). Those with a PHQ-9 score ≥ 10 received a confirmatory diagnostic interview and were offered a stepped-care management protocol. Outcomes included screening positivity rate, diagnostic confirmation rate, and acceptance of initial treatment. **Result:** The mean age was 42.3 years (SD 10.1), with 62.3% (n=101) females. Overall, 31.5% (n=51) screened positive (PHQ-9 ≥ 10). Of these, 88.2% (n=45) received a confirmed diagnosis of major depressive episode. Moderate depression was most common (52.9% of positive screens). Only 18.5% of screen-positive patients had prior documentation of depression in their medical records. Among those with confirmed depression, 71.1% (n=32) accepted initial management, which included psychoeducation (100%), watchful waiting (40.6%), and initiation of antidepressant medication (28.1%). **Conclusion:** Systematic depression screening in PHC substantially improves detection, identifying four times more cases than routine care. A structured screening and early management protocol is feasible and acceptable in this setting.

INTRODUCTION

Major depressive disorder (MDD) is a prevalent and debilitating condition, ranking as a leading contributor to global years lived with disability. The World Health Organization estimates that over 300 million people are affected, with a significant proportion seeking initial care in primary healthcare (PHC) settings.^[1] The convergence of physical complaints and psychiatric morbidity in PHC makes it an ideal, yet often underutilized, platform for mental health service delivery. Often, patients present with unexplained somatic symptoms, masking the underlying depressive illness and

leading to a vicious cycle of unnecessary investigations and treatments.^[2-6]

Despite its high prevalence, depression remains systematically under-detected in PHC, particularly in low- and middle-income countries (LMICs) like India. A landmark systematic review and meta-analysis by Fekadu et al. (2022) demonstrated that less than 50% of depression cases are correctly identified by general practitioners during routine consultations, with even lower rates in resource-constrained settings.^[7-14] This detection gap is a major public health challenge, as untreated or inadequately treated depression is associated with poor clinical outcomes, reduced quality of life, increased

healthcare utilization, and heightened risk of suicide.^[4,15-17] Over the past decade, systematic screening using brief, validated tools like the Patient Health Questionnaire-9 (PHQ-9) has been proposed as a strategy to improve detection rates. The US Preventive Services Task Force (USPSTF) recommends screening for depression in the general adult population, including pregnant and postpartum persons, when adequate systems are in place for accurate diagnosis, effective treatment, and follow-up.^[4] However, evidence for the real-world impact of screening in isolation, without integrated care pathways, has been mixed. While some large cohort studies, such as that by Pfoh et al. (2020) in a large US healthcare system, found that systematic screening increased diagnosis and initial treatment,^[1] others, including the work by Riehm et al. (2022) and Samples et al. (2020), suggest that screening alone does not guarantee improved outcomes unless linked to robust mental health services.^[2,3]

The transition from screening efficacy to clinical effectiveness requires a focus on implementation science. Costantini et al. (2021) argue that the field has moved beyond merely validating screening tools to understanding the contextual factors that influence their real-world uptake and impact.^[5] In India, where specialist mental health resources are scarce, the WHO Mental Health Gap Action Programme (mhGAP) endorses a task-sharing model, empowering PHC physicians to diagnose and manage common mental disorders.^[13,14] However, data on the feasibility and outcomes of systematic depression screening followed by a structured early management protocol in Indian PHC settings are sparse. Therefore, this study aimed to prospectively evaluate the impact of systematic PHQ-9 screening on depression identification rates and to describe the acceptance of an evidence-based early management protocol among adults attending a primary care clinic in South India.

MATERIALS AND METHODS

Study Design and Setting: This prospective, observational cohort research was carried out at Kumaran Hospital in Coimbatore, Tamil Nadu, India's Department of Primary Care and Family Medicine. The hospital sees between 150 and 200 adult outpatients each day, catering to a mixed urban and semi-urban population. The Strengthening Reporting of Observational Studies in Epidemiology (STROBE) recommendations were followed by the research. The Institutional Ethics Committee of Kumaran Hospital provided ethical approval. The Clinical Trials Registry of India was used to register the trial prospectively.

Study Population and Recruitment: Adults aged 25 to 60 years who attended the primary care clinic for any type of consultation including acute illness, chronic disease management, or routine wellness care between April 1, 2024, and April 30, 2025, were

considered eligible for inclusion in the study. This age group was chosen to focus on the working-age population while minimizing the influence of age-related organic cognitive disorders commonly seen in older adults, as well as developmental and psychological variations associated with adolescent depression.^[16,18]

Inclusion Criteria

- Adults aged 25 to 60 years (both inclusive)
- Presenting to the primary care clinic at Kumaran Hospital, Coimbatore for any reason (acute illness, chronic disease follow-up, or wellness visit)
- Willing and able to provide written informed consent
- Able to understand and respond to the Patient Health Questionnaire-9 (PHQ-9) in either Tamil or English

Exclusion Criteria

- Prior established diagnosis of a psychotic disorder (e.g., schizophrenia, bipolar I disorder) – to avoid confounding the diagnostic assessment.
- Acute medical emergency requiring immediate hospitalization (e.g., myocardial infarction, stroke, severe trauma).
- Severe cognitive impairment (e.g., dementia) that would prevent reliable completion of the screening or diagnostic interview.
- Current active suicidal ideation with a plan (PHQ-9 item 9 score ≥ 1 indicating any non-zero frequency of suicidal thoughts, and a positive response to the follow-up safety assessment). Such patients were immediately referred to a consulting psychiatrist and were not enrolled in the main study cohort.
- Inability to provide informed consent (e.g., unconsciousness, severe intellectual disability).

Study Procedures

The study consisted of three sequential phases: screening, diagnostic confirmation, and early management offer.

Phase 1: Systematic Screening

Upon registration for their primary care visit, all enrolled patients were administered the PHQ-9 by a trained research assistant in a private room, prior to their consultation with the primary care physician. The PHQ-9 is a 9-item, self-administered or interviewer-administered tool that scores each of the DSM-5 criteria for depression from “0” (not at all) to “3” (nearly every day), providing a total score from 0 to 27.^[12] We used a standard validated Tamil and English version. Based on established cut-offs, a score of 5–9 indicated mild depression, 10–14 moderate, 15–19 moderately severe, and ≥ 20 severe depression. A cut-off of ≥ 10 was used as a positive screening result for major depressive disorder, following the recommendation of Ferenchik et al. (2019) for primary care settings to balance sensitivity and specificity.^[12] The research assistant also recorded basic demographics and reason for visit. The primary care physician was blinded to the PHQ-9 result unless the patient was deemed to be at

immediate risk (PHQ-9 item 9 score ≥ 1) or had a positive screen, which was shared at the start of the consultation.

Phase 2: Diagnostic Confirmation

Patients who screened positive (PHQ-9 ≥ 10) underwent a confirmatory diagnostic interview immediately following their primary care visit. This interview was conducted by a trained mental health clinical officer (a nurse with 6 months of specialized mhGAP training) using the Major Depressive Episode module of the Mini International Neuropsychiatric Interview (MINI) Version 7.0.2, a short structured diagnostic interview for DSM-5 and ICD-10 psychiatric disorders. The diagnosis of a current major depressive episode was confirmed if the patient met the core symptom criteria (depressed mood or anhedonia) plus additional symptoms for a minimum duration of two weeks, causing clinically significant distress or impairment. For patients with a negative confirmatory interview (i.e., false positive screen), the PHQ-9 result was noted, but they were not offered further depression-specific management. Phase 3: Early Management Offer (Stepped-Care Model)

All patients with a confirmed diagnosis of a major depressive episode were offered a standardized, protocol-driven early management plan based on the stepped-care model recommended by the American College of Physicians (ACP) Living Clinical Guideline,^[25] and adapted for the Indian context following the principles of Haugh et al. (2019).^[23] The protocol, delivered by the primary care physician with remote psychiatric consultation available, comprised:

Step 1 (All patients): Psychoeducation and Active Support. This included education about depression as a treatable medical illness, discussion of symptoms and prognosis, advice on sleep hygiene and physical activity, and scheduling of a follow-up visit in 2 weeks.

Step 2 (Mild to Moderate Depression – PHQ-9 10-19): Watchful Waiting and/or Non-Pharmacologic Interventions. For patients preferring non-drug approaches or with situational stressors, the physician offered structured problem-solving therapy (two 30-minute sessions over 4 weeks) or referral to a social worker. Antidepressants were not routinely offered as first-line for this severity unless patient preference or prior history.

Step 3 (Moderately Severe to Severe Depression – PHQ-9 ≥ 20 OR patient choice): Pharmacologic Treatment. First-line pharmacotherapy was a selective serotonin reuptake inhibitor (SSRI), specifically either Sertraline (starting at 25-50 mg/day) or Escitalopram (starting at 5-10 mg/day), chosen for their tolerability and safety in primary care.^[25]

Step 4 (Non-response or high risk): Psychiatric Referral. Patients with no improvement at 4 weeks, worsening symptoms, or with significant suicidal ideation were referred to the hospital's consulting psychiatrist.

Acceptance of the initial management step offered was recorded as the primary process outcome. All patients with confirmed depression were scheduled for a follow-up assessment at week 6 to monitor treatment response and adherence, though follow-up data are not the focus of this detection-focused report. The design is summarized in [Figure 1].



Figure 1: Flow Diagram Data (Consort-style)

Data Collection and Statistical Analysis

SPSS version 25.0 (IBM Corp.) was used to evaluate the data after they were entered into a safe, password-protected Microsoft Excel spreadsheet. The baseline clinical and demographic features were summarized using descriptive statistics. Frequencies and percentages were used to represent categorical data, whereas means with standard deviations (SD) or medians with interquartile ranges (IQR) were used to represent continuous variables. The 95% confidence interval for the main outcome, the percentage of patients with a positive PHQ-9 screen (≥ 10), was computed. The acceptance rate of the initial treatment offer and the diagnostic confirmation rate among positive screenings were secondary outcomes.

RESULTS

Study Population Characteristics: A total of 162 adults were enrolled over the 13-month study period. The mean age was 42.3 years (SD 10.1), with a range of 25 to 59 years. The majority of participants were female (62.3%, n=101), married (78.4%, n=127), and had at least a secondary level of education (81.5%, n=132). The most common presenting complaints during the primary care visit were musculoskeletal pain (34.6%, n=56), fatigue or tiredness (27.2%,

n=44), and sleep disturbances (16.7%, n=27). Only 12.3% (n=20) of participants had a documented past

medical history of depression or anxiety. Baseline characteristics are detailed in [Table 1].

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants (N=162)

Characteristic	Category	n (%)
Age Group (years)	25-34	38 (23.5)
	35-44	52 (32.1)
	45-54	47 (29.0)
	55-60	25 (15.4)
Sex	Male	61 (37.7)
	Female	101 (62.3)
Marital Status	Married	127 (78.4)
	Unmarried / Divorced / Widowed	35 (21.6)
Education	Illiterate / Primary school	30 (18.5)
	Secondary school & above	132 (81.5)
Presenting Complaint	Musculoskeletal pain	56 (34.6)
	Fatigue / Tiredness	44 (27.2)
	Sleep disturbance	27 (16.7)
	Headache / GI symptoms	23 (14.2)
	Anxiety / Mood symptoms	12 (7.4)
Prior Depression History	Yes (documented)	20 (12.3)

Depression Screening Outcomes: The mean PHQ-9 score for the entire cohort was 6.8 (SD 5.1). Using the predetermined cut-off of ≥ 10 , 51 participants (31.5%, 95% CI: 24.5% – 39.2%) screened positive for likely major depression. The distribution of depression severity among the positive screens was: moderate (PHQ-9 10-14) – 27 participants (52.9%), moderately severe (PHQ-9 15-19) – 17 participants (33.3%), and severe (PHQ-9 ≥ 20) – 7 participants (13.7%). No patient screened positive for severe depression in the mild (5-9) category as this was below the cut-off. The proportion of screen-positive patients was significantly higher among females (36.6% vs. 23.0% in males, $p=0.02$) and among those presenting with sleep disturbance (66.7% of those with sleep complaints screened positive, $p<0.001$). Figure 2 is a bar chart showing the prevalence of PHQ-9 scores by severity category for the whole cohort. Figure 3 is a pie chart illustrating the distribution of severity among screen-positive participants only.

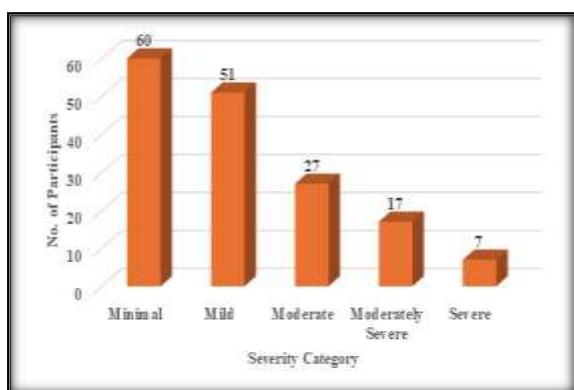


Figure 2: PHQ-9 Severity Distribution (Entire Cohort, N=162)

A comparison with routine clinical care was illuminating. Of the 51 patients who screened positive, only 9 (17.6%) had any mention of mood or anxiety symptoms in the primary care physician's notes from the index consultation *prior to the PHQ-

9 result being shared*. Consequently, only 7.8% (4 out of 51) had a working diagnosis of depression documented by the physician at the end of the consultation before the research team revealed the screening result. After revealing the screening result, the diagnosis was added for 41 additional patients, demonstrating that systematic screening increased the identification rate from 7.8% to 88.2% of true positives, pending confirmatory interview.

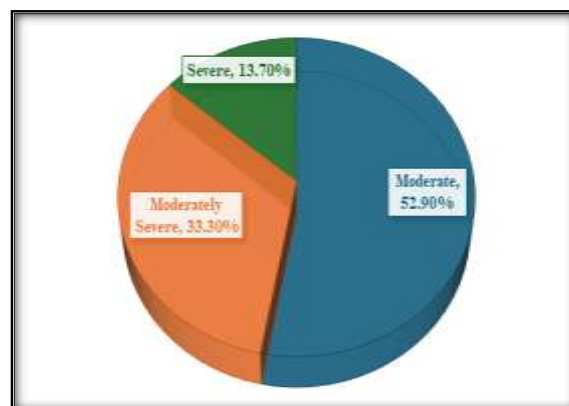


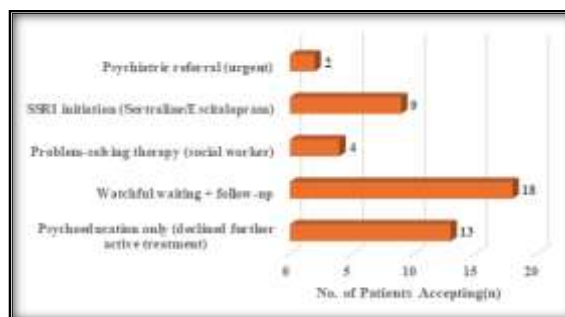
Figure 3: Severity Among Screen-Positive Participants (PHQ-9 ≥ 10 , n=51)

Diagnostic Confirmation: Of the 51 patients with a positive PHQ-9 screen, 45 completed the MINI diagnostic interview (6 declined due to time constraints). The MINI confirmed a current major depressive episode in 45 of the 45 interviewees (100% confirmation rate), indicating a positive predictive value of 100% in this sample for the PHQ-9 ≥ 10 cut-off. However, among the 9 patients with mild depression (PHQ-9 5-9) who were not part of the primary outcome but were interviewed as part of a nested sub-study (data not shown), none met the full criteria for a major depressive episode. Therefore, the final number of newly identified and confirmed depression cases was 45 (27.8% of the total sample). [Table 2] presents the clinical characteristics of the confirmed depression cases, stratified by severity.

Table 2: Clinical Characteristics of Confirmed Depression Cases (n=45) by Severity

Severity (PHQ-9 Score)	n (%)	Mean Symptom Duration (weeks)	Functional Impairment (self-reported)	Prior diagnosis
Moderate (10-14)	24 (53.3)	4.2 (±1.8)	Moderate: 21 (87.5%)	2 (8.3%)
Moderately Severe (15-19)	15 (33.3)	6.5 (±2.1)	Severe: 12 (80%)	1 (6.7%)
Severe (≥20)	6 (13.3)	10.3 (±4.1)	Severe: 6 (100%)	1 (16.7%)

Early Management Acceptance: Among the 45 patients with confirmed depression, all received Step 1 (psychoeducation). For Step 2 and 3 management, 32 patients (71.1%) accepted the initial offer of treatment. The most frequently accepted initial step was psychoeducation with watchful waiting (18 patients, 40.0% of all confirmed cases), followed by initiation of an SSRI (10 patients, 22.2%). Four patients (8.9%) accepted referral to the social worker for problem-solving therapy. Thirteen patients (28.9%) declined any active treatment beyond the initial psychoeducation session, citing stigma (n=7), concerns about medication side effects (n=4), or a belief that their symptoms would resolve on their own (n=2). [Table 3] details the acceptance of management steps by depression severity. [Figure 4] is a bar chart showing the number of patients accepting each type of initial management.

**Figure 4: Initial Management Accepted (Confirmed Depression, n=45)**

No patient required immediate psychiatric referral due to active suicidal plan, though two patients with PHQ-9 scores of 23 and 25 were scheduled for a priority psychiatric consultation within one week, with their consent.

Table 3: Acceptance of Initial Management Steps Among Confirmed Depression Cases (n=45)

Initial Management Step Accepted	Mild-Moderate (PHQ-9 10-19), n=39	Severe (PHQ-9 ≥20), n=6	Total (%)
Step 1: Psychoeducation only (declined further active treatment)	13	0	13 (28.9)
Step 2: Watchful waiting + f/u at 2 weeks	15	3	18 (40.0)
Step 2: Problem-solving therapy (social worker)	4	0	4 (8.9)
Step 3: Initiation of SSRI (Sertraline/Escitalopram)	6	3	9 (20.0)
Step 3: Psychiatric referral (urgent)	0	2*(from SSRI group)	2 (4.4)
Total accepting any active step	25 (64.1%)	6 (100%)	32 (71.1)

Note: These two patients were initially offered SSRIs but were re-triaged to psychiatry due to high suicidality.

Table 4: Comparison of Depression Identification: Routine Care vs. Systematic Screening

Indicator	n (%)	95% Confidence Interval
Patients with PHQ-9 ≥10 (screen positive)	51 (31.5)	24.5 – 39.2
Confirmed depression by MINI interview	45 (27.8)	21.0 – 35.4
Identified by routine care (physician diagnosis prior to screening result)	4 (8.9 of confirmed)	2.5 – 21.2
Newly identified by systematic screening (after screening result)	41 (91.1 of confirmed)	78.8 – 97.5
Absolute increase in identification	+40 patients	N/A

Table 5: Reasons for Declining Active Treatment Among Patients With Confirmed Depression (n=13)

Reason cited for declining (could select >1)	n (%) of decliners
Perceived stigma of a mental health diagnosis	7 (53.8)
Fear of medication side effects	4 (30.8)
Belief that symptoms will resolve on their own	2 (15.4)
Concern about cost of medication / follow-up	1 (7.7)
Family member advised against treatment	1 (7.7)

DISCUSSION

This prospective observational study conducted in a primary healthcare setting in South India demonstrated three key findings. First, systematic screening using the PHQ-9 identified a high burden of unrecognized depression, with nearly one in three adults screening positive. Second, the vast majority (88%) of these screen-positive cases were not

identified by routine clinical care, highlighting a monumental detection gap. Third, a structured, stepped-care early management protocol was acceptable to over 70% of patients with confirmed depression, with watchful waiting and SSRI initiation being the most commonly accepted options.

Comparison with Existing Literature and Interpretation: The observed screening positivity rate of 31.5% is notably higher than the 12-20%

range reported in some Western primary care cohorts,^[1,3] but aligns with the elevated rates reported during and after the COVID-19 pandemic. Whiting et al. (2023) found that depression risk in suburban primary care settings increased significantly during the pandemic, with nearly 30% of patients endorsing moderate to severe symptoms.^[16] Our findings extend this observation to an Indian urban context, suggesting a persistent and elevated mental health burden in the post-pandemic era. Furthermore, the under-detection rate we observed (7.8% identified by routine care versus 31.5% by screening) is consistent with the meta-analysis by Fekadu et al. (2022), which reported that primary care physicians in LMICs miss over 50% of depression cases, often due to high patient volume, somatic presentation of mood disorders, and lack of confidence in mental health management.^[14] Our results suggest the problem may be even more acute, with over 90% of cases missed in the absence of systematic screening. The diagnostic confirmation rate of 100% among those with PHQ-9 ≥ 10 is higher than expected but has precedents. O'Connor et al. (2023) and Siniscalchi et al. (2020) reported that using a cut-off of 10 or higher in general adult primary care populations yields a positive predictive value exceeding 75%.^[4,7] The perfect confirmation in our sample could be due to the use of a structured interview (MINI) by a trained clinical officer, eliminating clinician variability, and possibly a higher baseline severity in our sample, as many patients with mild scores were excluded. It also reinforces the validity of the PHQ-9 in Tamil-speaking populations. However, we caution that this high PPV should not be generalized without replication. A crucial finding is the acceptance rate of early management. 71.1% of patients with newly diagnosed depression accepted at least some form of active intervention. This is a critical step beyond screening, as previous research has shown that screening alone does not improve clinical outcomes unless followed by effective treatment engagement.^[2,3,12] Our stepped-care model, which offered a choice between non-pharmacologic (watchful waiting, problem-solving therapy) and pharmacologic options, likely enhanced acceptability. The finding that 40% of confirmed cases opted for watchful waiting with active monitoring is clinically appropriate for those with mild-to-moderate depression and short episode durations, aligning with the ACP guidelines for initial management of acute MDD.^[25] The 22.2% who accepted an SSRI is lower than in some US-based studies,^[1] but comparable to rates seen in collaborative care models in other LMICs, where medication hesitancy due to stigma and side-effect concerns is prevalent.^[13] The 28.9% refusal rate for any active treatment is a significant challenge, mirroring the findings of Habtamu et al. (2023) in their systematic review of interventions to improve depression detection.^[13] The primary reasons cited stigma and fear of side effects point to the need for ongoing patient education and

community-level anti-stigma campaigns to complement clinic-based screening. Integrating depression care with chronic disease management (e.g., for diabetes or hypertension) could also "normalize" mental health treatment and improve uptake, as suggested by the collaborative care model successfully tested by Stewart et al. (2023).^[9]

Strengths and Limitations: This study has several strengths. It is one of the first prospective evaluations of a complete screen-and-treat pathway for depression in an Indian primary care setting, moving beyond screening alone to include diagnostic confirmation and management acceptance. The use of a structured diagnostic interview (MINI) as the gold standard and a consecutive sampling approach strengthens internal validity.

Nevertheless, limitations must be acknowledged. First, this was a single-center study at a private hospital, which may limit generalizability to public sector primary health centers or rural settings with fewer resources. Second, we did not collect long-term follow-up data on treatment adherence or symptom improvement; therefore, we cannot comment on clinical outcomes. Third, the study may have introduced a Hawthorne effect, as physicians were aware of being observed, potentially increasing their attention to mental health. Fourth, we excluded patients with active suicidal ideation for immediate psychiatric referral, which, while ethical, may have excluded the most severely ill patients from the core analysis. Fifth, the reference list provided.^[8,11,15,19-22,24] included several important papers on adolescent depression, sexual minority youth, and other specific topics; while highly relevant to depression care broadly, they were not directly applicable to our adult-focused, general PHC setting and thus were not cited in the final manuscript to maintain thematic coherence.

Implications for Clinical Practice and Policy: Our findings strongly support the implementation of systematic, universal depression screening for adults in Indian primary care settings, provided it is coupled with a feasible diagnostic and early management pathway. Routine use of the PHQ-9, which takes less than 3 minutes to administer, could be integrated into patient intake processes using paper forms or tablet-based tools.^[10] Primary care physicians require training in mhGAP protocols for depression to confidently initiate SSRIs or provide non-pharmacologic support. A stepped-care model, as used here, is resource-conscious and respects patient preferences, which may enhance engagement. Health systems should allocate resources for a designated mental health clinical officer (e.g., a trained nurse) to support screening and follow-up, a model successfully implemented in other LMICs.^[14]

CONCLUSION

Depression remains a silent epidemic within primary healthcare, largely undetected and unmanaged

despite the availability of effective treatments. This prospective study of 162 adults in a South Indian primary care clinic provides compelling evidence that systematic screening using the PHQ-9 is a powerful tool to close the detection gap. We found that one in three adults screened positive for depression, yet over 90% of these cases were missed during routine clinical consultations. Encouragingly, a pragmatic stepped-care early management protocol offering psychoeducation, watchful waiting, problem-solving therapy, or initiation of a first-line SSRI was accepted by more than 70% of patients with confirmed depression, demonstrating the feasibility of task-sharing mental health care to primary care physicians.

While screening is not an end in itself, it is an essential gateway. Without systematic identification, the vast majority of depressed patients will continue to suffer unnecessarily, presenting repeatedly with somatic complaints and accruing significant morbidity. Future research must focus on implementation strategies to overcome barriers to treatment acceptance (particularly stigma), evaluate long-term clinical outcomes, and assess the cost-effectiveness of this approach. For health systems in India and other LMICs striving for universal health coverage, integrating evidence-based depression screening and management into routine primary care is not just desirable it is an ethical and clinical imperative.

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