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Common Mental Disorders among Women in Rural Western India: association with selfperceived health status, healthcare utilization, and care related costs.

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Keywords: Common Mental Disorders, Health Status, Healthcare Expenditure Healthcare Behavior, Rural India, Reproductive-aged Women.

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ABSTRACT

Objectives

To determine the prevalence of common mental disorders (CMD) and characterize its association with self-reported health status, healthcare utilization in the previous year, and portion of yearly household income spent on healthcare costs among women from rural western India based on a representative, cross-sectional survey.

Setting

Surveys were conducted in the waiting area of various outpatient clinics at a tertiary care hospital and in 16 rural villages in the Anand district of Gujarat, India.

Participants

700 Gujarat-speaking women between the ages of 18-45 years who resided in the Anand district of Gujarat, India were surveyed in a quasi-randomized manner. Data from 658 were used in this analysis; 19 surveys were excluded due to incompleteness, 18 participants were excluded because they were visiting hospitalized patients, and five surveys were classified as outliers.

Primary and secondary outcomes measures

Association of CMD with 1) number of healthcare visits in the prior year; 2) self-reported health status; and 3) portion of yearly income expended on healthcare.

Results

Overall, 155 (22.8%) participants screened positive for CMD with most (81.9%) not previously diagnosed despite contact with healthcare provider in the prior year. On adjusted analyses, positive screening for CMD was associated with worse category in self-reported health status (cumulative OR= 9.39; 95% CI: 5.97-14.76), higher portion of household income expended on healthcare (cumulative OR = 2.31; 95% CL: 1.52-3.52), and increased healthcare visits in the prior year (Incidence Rate Ratio = 1.24; 95% CI: 1.07-1.44).

Conclusions

The high prevalence of CMD among rural women in India that is undiagnosed and associated with adverse health and financial indicators highlights the individual and public health burden of CMD. There is a need for innovative programs that leverage technology and care management to overcome limited mental health resources.

Keywords: Common Mental Disorders, Health Status, Healthcare Expenditure Healthcare Behavior, Rural India, Reproductive-aged Women.

Strengths and limitations of this study

- Our novel dataset contains information about health status and healthcare of reproductive-aged women in rural Indian, an underserved and understudied population.
- This is the first study to report the association of common mental disorders (CMD) with self-reported health status, healthcare expenditure, and healthcare utilization among women in rural India.
- The multivariable negative binomial and ordinal logistic regression allowed robust estimation of disease-adjusted association, which preserved the data structure of self-reported measures.
- We are limited by our cross-section study design that limits causal interpretation. of L. nditure IL reosts are out L However, identification of the associations between vulnerable CMD positive women and healthcare related expenditure holds significance in the context of a system where the majority of healthcare costs are out of pocket.

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INTRODUCTION

Depression is the leading cause of total years lived with disability globally. [1,2] In developed countries, depression has been associated with lower health status, increased ambulatory and emergency hospital visits, loss in productivity, and greater healthcare costs.[3,4] Despite recent estimates suggesting that low and middle-income countries (LMIC) experience over 80% of the worldwide burden attributed to depression,[1,5] there is disproportionately limited data regarding consequences from these countries. Within LMIC, further disparities exist such that regions with a relatively greater burden of common mental disorders (CMD) remain understudied.

While there is a higher prevalence of CMD among women living in rural, patriarchal regions outside of southern India,[6] the majority of mental health studies in India are conducted in urban settings, south India, or in the comparatively progressive state of Goa.[7,8] The western state of Gujarat experiences a greater prevalence of CMD in comparison to Goa and South India; additionally, there are reports of tremendous stigma against mental disorders among community members as well as healthcare providers.[9–12] This stigma could make detection of CMD less likely and exacerbate its consequences. Because healthcare priorities are often dictated by disease burden and its impact on individuals and their communities, information about CMD prevalence and its associated healthcare outcomes is necessary to guide prioritization of mental health programs.

The goal of this study was to determine the prevalence of CMD and characterize its association with self-reported health status, healthcare utilization in the previous year, and portion of yearly household income spent on healthcare costs among women from rural western India based on a representative, cross-sectional survey.

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METHODS

Setting and Study Design: Data was collected through a cross-sectional survey among women currently living in rural settings in the Anand district of Gujarat, India. Trained interviewers conducted face-to-face surveys in Gujarati, the local language. Seven-hundred eligible women between the ages of 18-45 years, that could comprehend and speak Gujarati, and had a rural residence within the Anand district, consented and participated in the study. Participants were recruited from two different settings: 1) Shree Krishna Hospital, a tertiary care center serving the local rural population; and 2) 16 villages within a 20-kilometer radius from the hospital. In the hospital clinic waiting areas, participants were quasi-randomly selected with interviewers by approaching every third woman in the outpatient waiting area. Interviews were conducted in the waiting area but away from participants' family members and other patients in the clinic. Prior to recruitment in the villages, the layout of each village was obtained. Every third household in each of the village's colonies was approached and the first female who encountered the interviewer was asked to participate in the study. Community interviews were conducted at participants' residences. In both settings, two research supervisors, a male and a female, ensured privacy of all participants. The data collection was funded by an institutional travel grant by Boston University. Boston University Institutional Review Board and the Human Research Ethics Committee of HM Patel Center for Medical Care and Education reviewed the study independently and approved it.

Data Collection: The study survey was drafted in English and underwent two iterations of translation back and forth between Gujarati and English. The survey was comprised of 150 items total and was divided into five modules: a) health status, b) current and past medical history, c) lifestyle choices, d) healthcare seeking behavior, and e) affordability of healthcare. Five trained

 female interviewers conducted all interviews from October 1 – October 13, 2011. An average survey lasted 20-30 minutes. Of the 700 participants interviewed for the study, data from 658 were used in this analysis; 19 surveys were excluded due to incompleteness, 18 participants were excluded because they were visiting hospitalized relatives, and five surveys were classified as outliers due to their healthcare behavior (these participants had more than 20 clinical visits in the previous year due to serious health conditions).

Data Variables: The outcome of CMD was determined using the World Health Organization (WHO) Self-Reporting Questionnaire (SRQ-20).[13] SRQ-20 demonstrated excellent internal reliability in our population as measured by the Kuder Richardson 20 score of 0.90. Similar to prior studies, participants who responded 'yes' to eight or more questions were considered as screening positive for CMD.[14]

Number of healthcare visits in the previous year was determined by participant self-report. Health status was assessed by using the first question from the SF-12 instrument: "*In general, would you say your health is*"; possible choices were (a) Excellent, (b) Very Good, (c) Good, (d) Fair, or (e) Poor. Expenditure of household income on healthcare was measured by asking participants, "What most closely estimates the portion of your yearly household income spent on healthcare?" with choices offered as (a) none, (b) less than ¼, (c) ¼ to less than ½, (d) ½ to ³/₄, or (e) more than ³/₄. Potential associations between CMD and healthcare utilization, self-reported health status, and expenditure on healthcare can be confounded by the presence of other diseases, age, marital status, income, and education level. Therefore, these factors were adjusted using multivariable methods. Disease burden was based on self-report of current conditions or past diagnoses of chronic diseases excluding any mental health disorders (see footnotes in Table 1 for more details). Disease burden was estimated as an aggregate grouped into four categories: no

disease, one disease, two diseases, and three or more diseases. Education of participants was categorized as $< 7^{th}$ grade, 7^{th} grade- 12th grade, or > 12th grade. As described elsewhere,[15] monthly household income was transformed into income/person/day values to account for variation in the household size. Daily per capita income was subsequently converted to US dollars using the average currency exchange rate from 2011, the year the study was conducted and categorized into three levels (< \$0.25, \$0.25-\$1.25, >\$1.25).

Statistical Analyses: Descriptive data analyses were performed to assess the distribution of potential confounders with respect to CMD. Frequencies and percentages were calculated for categorical variables; associations with CMD were assessed using chi-square test for independence of attributes or Fischer's exact test. Bivariate association of age and number of visits to clinic in the previous year was assessed using a one-way analysis of variance test. Ordered logistic regression analyses were used to quantify the relationship of positive CMD screen with health status and household income spent on healthcare. Few participants reported poor health status; therefore, we grouped self-reported fair and poor health status. Similarly, few participants reported spending none or >3/4 of their household income on healthcare and therefore they were grouped with adjacent categories. Violation of parallel regression assumptions were ruled out using Brant test for health status ($\chi^2 = 29.76$, df = 22; p = 0.67) and income spent on healthcare outcomes ($\chi^2 = 9.37$, df = 22; p = 0.67). The association of CMD and number healthcare visits in the previous year was evaluated using negative binomial regression modeling. A negative binomial model was selected over Poisson to account for the over dispersion in the outcome (α =0·23; χ^2 = 150.05, p < 0·001); improvement of model fit using zero inflated negative binomial regression was tested and ruled out using vuong test (z = 0.42, p =0.34). Unadjusted and adjusted incidence rate ratios (IRR) were calculated and interpreted as a

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count multiplier for the number of healthcare visits in the previous year. All three models adjusted for number of co-morbid conditions, age, income, education, and marital status.

RESULTS

Using the SRQ-20 to assess presence of CMD, 155 (22.8%) participants screened positive having answered yes to at least eight of 20 questions. On average, participants visited a healthcare provider more than three times in the previous year. The majority of the respondents considered their health status less than very good (i.e.; good or fair/poor), and over 60% reported spending less than a quarter of their yearly income on healthcare.

Table 1 presents characteristics of participants who screened positive for CMD compared with participants screening negative. Increased levels of education and household income were associated with decreased likelihood of screening positive for CMD. More than four out of every five (81·3%) respondents who screened positive for CMD did not report a diagnosis of depression or other mental health disorder even though all but four of these women reported visiting a healthcare provider at least once in the past year (results not shown).

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	Total	CMD Screening (col %)		
	N	Positive	Negative	_ р
Participants (N)	658	155	503	
# Clinic Visits ^a (mean(sd))	3.6 (2.8)	3.2(2.5)	4.6(3.5)	$0.001^{\#}$
Health Status				
Excellent	166	1.3	32.6	<0.001*
Very Good	95	3.9	17.7	
Good	249	34.8	38.8	
Fair/Poor	148	60.0	10.9	
HHI Spent on Healthcare ^b				
Less than 1/4	403	36.8	68.9	< 0.001
1/4 to 1/2	184	38.0	24.9	
More than $1/2$	70	25.2	6.2	
# Diseases or Conditions ^c				
Zero	221	3.9	42.2	< 0.001*
One	155	17.4	25.8	
Two	148	28.4	20.9	
Three or more	134	50.3	11.1	
Current Depression				
Yes	34	18.7	1.0	N/A
Age (years)				
18-25	226	28.6	36.3	0.18
26-35	249	39.6	37.5	
36-45	181	31.8	26.3	
Education				
< 7th Grade	162	34.8	21.6	
7th - 12th Grade	356	55.5	53.9	< 0.001
> 12th Grade	138	9.7	24.5	
Marital Status				
Single	97	8.4	16.7	0.03*
Married	541	88.3	80.5	
Divorced or Widowed	19	3.3	2.8	
Daily Income Per Person				
< \$0.25	49	13.5	5.9	0.01
\$0.25-1.25	369	56.1	58.6	
>\$1.25	218	30.4	35.5	

a: Number of clinic visits in the previous year based on self-report

b: Portion of yearly household-income spent on healthcare expenditure c: Participants were asked to identify using a list of 33 non-psychiatric conditions and diseases. 22 conditions and diseases reported at least once by any participant; these were reviewed by trained clinicians to identify chronic conditions. Based on the review, an aggregate variable to represent chronic disease burden was generated; it comprised of cardiovascular problems (coronary heart disease, hypertension, positive history of heart attack or related condition), pulmonary problems (difficulty breathing, chronic allergies, asthma, or chronic bronchitis), musculoskeletal pain (chronic back problems, arthritis, difficulty opening mouth, or limited mobility due to pain), toothaches, anemia, and diabetes.

Fischer's Exact Test; [#]ANOVA

The adjusted association between CMD status and health status as well as portion of household income spent on healthcare is presented in Table 2. After controlling for confounders, screening positive for CMD was associated with more than an eight-fold increase in the cumulative odds of reporting a worse health status (cumulative OR (cumOR)= 9.39; 95% CI: 5.97-14.76) and a two-fold increase in the cumulative odds of reporting a higher category of income expenditure on healthcare (cumOR = 2.31; 95% CL: 1.38-3.06). Increasing number of comorbid non-psychiatric conditions were associated with self-report of lower health-status and greater portion of income spent on healthcare. In comparison to participants with no comorbid non-psychiatric conditions, participants who reported 3 or more had more than twice the cumulative odds of reporting a poorer health status (cumOR = 2.61; 95% CL: 1.60-4.24) and more than three times greater cumulative odds of spending a higher portion of their yearly income on healthcare (OR = 3.46; 95% CL 2.05 - 5.84).

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Table 2: Ordinal Logistic Regression Models for the Association between Common Mental Disorder (CMD) and a) Self-Reported Health Status and b) Yearly Income Spent on			
Healthcare			
	Self-Reported Health Status ^a	Yearly Income spent on healthcare ^b	
	CumOR (95% CL)*	CumOR (95% CL)*	
CMD Screen: Negative (ref)			
Positive (SRQ-20 \ge 8)	9.39 (5.97-14.76)	2.31 (1.52-3.52)	
Disease or Conditions: Zero			
(ref)			
One	1.19 (0.80-1.77)	1.26 (0.76-2.07)	
Two	1.64 (1.08-2.47)	3.07 (1.90-4.96)	
Three or More	2.61 (1.60-4.24)	3.46 (2.05-5.84)	
Ordered categories: a= Excellent, Very Good, Good, Fair/Poor; $b = \langle 1/4, 1/4-1/2, \rangle 1/2$			
*CumOR: Cumulative odds ratio also adjusted for age, income, education, and marital status.			

Results from negative binomial regression models are reported in Table 3. Before adjusting for confounding, CMD status was associated with a 40% increase in the number of clinical visits in the previous year (IRR = 1.42; 95% CI: 1.25-1.61). Participants who reported experiencing multiple non-psychiatric comorbidities were also more likely to have greater number of clinic visits in the previous year (two diseases: IRR = 1.27 [1.07-1.50]; three or more diseases: IRR = 1.44 [1.25-1.65]).

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Table 3: Multivariable negative binomial regression model estimates of count multiplier (IRR^a) for number of clinical visits in the previous year.

	unadjusted	_adjusted* (n=632)	
	IRR (95% CL)	IRR (95% CL)	
CMD: Negative (ref)			
Positive	1.41 (1.24-1.60)	1.24 (1.07-1.44)	
Comorbid Conidtions: No	one (ref)		
1	1.10 (0.94-1.28)	1.11 (0.95-1.29)	
2	1.25 (1.07-1.46)	1.18 (1.00-1.39)	
3 or more	1.47 (1.26-1.72)	1.27 (1.06-1.52)	
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a: IRR = incidence rate ratio is calculated by exponentiating beta co-efficients of count models. IRR can be interpreted as count multipliers. For example, screening positive for CMD is associated with a 42% increase in the number of clinical visits in the previous in comparison to those who do not screen positive (unadjusted estimates) *Also adjusted for education, age, income, and marital status

DISCUSSION

In this sample of reproductive-aged women from rural western India, approximately one out of every four participants screened positive for CMD. Despite visiting a healthcare provider at least once in the previous year, the majority did not report a diagnosis of depression or other mental health disorder. Positive CMD status was associated with an increased number of healthcare visits, worse self-reported health status, and higher portion of household income expended on healthcare. Together, these findings underscore significant negative outcomes associated with CMD experienced by women of reproductive age from rural western India.

Our high prevalence of undiagnosed CMD (81·3%) is similar to the 79.0% depression prevalence reported by Kohli et al for primary care attendees from another rural region in India.[16] The high rates are likely to be driven by two main factors. First, compared to western societies, people in India are more likely to attribute mental illness to personally controllable factors and thus mental health in rural India is associated with a tremendous amount of stigma Page 13 of 25

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and social disadvantage.[9,17] Consequently, Indians may be less willing to disclose psychological symptoms. Indeed, studies have shown that most Indian patients suffering from mental disease present with somatic symptoms, which may increase the likelihood that CMD goes undetected.[18–20] Second, there is a scarcity of mental healthcare providers in India and other healthcare providers do not receive adequate mental health training.[21] Thus, in primary care settings mental illness may not be considered in the differential diagnoses, especially in the context of an atypical presentation, leading to inadequate identification of mental diseases.[22]

In addition to documenting a high prevalence of undiagnosed CMD, we also found that CMD was associated with worse self-reported health. The association of CMD with worse self-reported health was more than three times the magnitude of the association of CMD with two or more non-psychiatric co-morbidities. By comparison, Moussavi et al found that depression produced equal health decrement as having two non-psychiatric conditions concurrently.[23] This disparity reveals suggests that CMD may have a greater impact on the health of an individual than to non-psychiatric conditions among women in this community. Poor appraisal of personal health could lead to a greater healthcare utilization which can increase healthcare expenditure in India where the majority of the healthcare costs are out of pocket.[15,24]

Our findings suggest that women with CMD visited their providers more frequently and were more likely to spend a larger portion of their household income on healthcare. The association between CMD and healthcare cost also could be self-perpetuating. Women may present to primary clinics with somatic rather than psychological symptoms, which may lead to underdiagnosis and treatment of CMD. Patients and their medical providers may continue to search

for a physical cause, incurring healthcare costs and a greater number of healthcare visits, while the underlying mental illness remains undiagnosed and unaddressed.[22,25]

 Due to healthcare related costs, 63 million people in India fall below the poverty line every year.[26] This is expected to rise given the inevitable increase in the prevalence of chronic, noncommunicable diseases in India, which carry a greater financial burden than communicable diseases.[27,28] Treating CMD with pharmacological and psychological therapies has been shown to reduce the economic burden of healthcare among adults. Thus, treatment of mental illness could break this vicious cycle of poverty and CMD. The Indian government recently proposed to revamp its mental health services through the National Mental Health Policy of India (NMHPI). NMHPI proposes to increase the number of mental healthcare providers and expand coverage from 182 to 648 districts and support 11 centers of excellence in mental health to train the next generation's mental healthcare providers.[29] Despite the laudable NMHPI proposal, the urgent needs of rural Indian women may continue to go unaddressed because the proposal may be difficult to implement due to lack of funding and a cohesive implementation plan.[30]

Integration of mental healthcare into primary care could provide a solution because women suffering from mental illness most often present to primary care settings.[31,32] Depression screening needs to be done in conjunction with a systematic approach to ensuring adequate access to mental health assessment and care.[33] It is well-established that integrated care models, such as collaborative care, effectively integrate depression and primary care and improve clinical outcomes.[34] Such approaches have also been tested in India; Patel and colleagues tested a collaborative stepped care (CSC) model that included four levels of referral before a clinical specialist became involved in care.[35] The CSC model begins with CMD screening for adult

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patients that present to clinic with a village health worker, and progresses through therapeutic steps of increasing intensity including Yoga, behavioral, and pharmacologic interventions. Patients who do not respond to a less intense treatment are stepped up to a higher intensity therapeutic option. The CSC model improves in mental illness over a 6-month period and holds promise as an effective mechanism to improve mental health in rural India.[36] However, the wide implementation of the CSC model in India is lacking and has been limited to Goa and South India, two regions in India that face a comparatively lower burden of mental diseases.[37,38] Despite treatment success, many collaborative care models depend on care management facets that are not reliably reimbursed and therefore their broad implementation, dissemination, and associated treatment improvement are not realized.[39] The term "voltage drop" has been used to describe the less robust results found when collaborative care approaches are implemented in low resource real-world settings.[40] Thus, there is need for cost-effective treatment plans that leverage primary care providers and staff already working in the primary care setting.

The findings from our study must be interpreted in the context of its limitations. We identified CMD status using a validated questionnaire instead of a structured clinical interview. Our data was collected through a cross-sectional survey and thus we cannot comment on the causal relationship of our findings. Presence of comorbidities among our participants was captured through self-report and therefore is vulnerable to differential recall with CMD positive women potentially over-reporting their conditions. However, such misclassification would likely bias our estimates toward the null hypotheses. Our estimates of household expenditure on healthcare was based on a single question and had broad categories and therefore may lack precision; however,

in the context of rural Gujarat, this instrument provides information about healthcare costs that is difficult to capture and not available in other databases.[32]

In conclusion, we found a high burden of CMD among women in rural India that is undiagnosed and is associated with adverse impacts on overall health and economic well-being. Our findings suggest that there is need to screen, assess, and manage CMD in primary healthcare and community-based settings in India. This could, in turn, improve overall health status and reduce healthcare related economic burden.

Contributors' Statement:

Apurv Soni: Soni conceptualized, designed, and implemented the study in India. Soni carried out the initial analyses, drafted the initial manuscript, and approved the final manuscript as submitted.

Nisha Fahey: Fahey conceptualized, designed, and implemented the study in India. Fahey provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Nancy Byatt: Byatt provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Anusha Prabhakaran: Prabhakaran provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Tiffany Moore Simas: Moore Simas provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jagdish Vankar: Vankar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Ajay Phatak: Phatak conceptualized, designed, and implemented the study in India. Phatak provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

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Eileen O'Keefe: O'Keefe conceptualized and designed the study. O'Keefe provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jeroan Allison: Allison provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Somashekhar Nimbalkar: Nimbalkar conceptualized, designed, and implemented the study in India. Nimbalkar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Competing Interests: I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: None

Data sharing statement: No additional data are available

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	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstrac
		Page 2: ABSTRACT (Methods)
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
		Page 2: ABSTRACT (Methods and Results)
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Buckground/Tutionale	-	Page 3: INTRODUCTION (1 st and 2 nd Paragraph)
Objectives	3	State specific objectives, including any prespecified hypotheses
Objectives	3	Page 3: INTRODUCTION (3 rd Paragraph)
	\bigcirc	Page 3. INTRODUCTION (5 Paragraph)
Methods		
Study design	4	Present key elements of study design early in the paper
		Page 4: METHODS (Setting and Study Design)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment
		exposure, follow-up, and data collection
		Page 4: METHODS (Setting and Study Design)
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of
		participants
		Pages 4 and 5 : METHODS (Setting and Study Design, Data collection)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect
		modifiers. Give diagnostic criteria, if applicable
		Pages 5 and 6 : METHODS (Data Variables)
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there
		more than one group
		Pages 5 and 6 : METHODS (Data Variables)
Bias	9	Describe any efforts to address potential sources of bias
		Pages 5 and 6 : METHODS (Data Variables)
Study size	10	Explain how the study size was arrived at
		We did not provide calculations for sample size for this study in the manuscript
		because the sample size for data collection was
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
Qualificative variables		describe which groupings were chosen and why
		Pages 5 and 6 : METHODS (Data Variables)
Statistical methods	12	(<i>a</i>) Describe all statistical methods, including those used to control for confounding
Statistical methods	12	Pages 6: METHODS (Statistical Analyses)
		(b) Describe any methods used to examine subgroups and interactions
		Pages 6: METHODS (Statistical Analyses)
		(c) Explain how missing data were addressed
		Pages 6: METHODS (Statistical Analyses)
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy
		We did not use sample survey weights in our study
		(e) Describe any sensitivity analyses

Results

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Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
		13:a-c) All participants were interviewed once when their eligibility was examined
		prior to interview. Details regarding participant participation is provided on pages 4 and 5 : METHODS (Setting and Study Design, Data collection)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and
		information on exposures and potential confounders $T = 10$, $D = C = 10^{10}$ and $T = 10^{10}$
		Pages 7 and 8: RESULTS (1 st and 2 nd paragraph; Table 1)
		(b) Indicate number of participants with missing data for each variable of interest Page 8: RESULTS (Table 1)
Outcome data	15*	Report numbers of outcome events or summary measures
		Page 8: RESULTS (Table 1)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
		their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included
		Pages 9 and 10: RESULTS (3 rd and 4 th paragraph; Tables 2 and 3)
		(b) Report category boundaries when continuous variables were categorized
		Page 8: RESULTS (Table 1)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period
		Not relevant for analyses provided
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and
		sensitivity analyses
		Not applicable
Discussion		
Key results	18	Summarise key results with reference to study objectives
		Page 11: DISCUSSION (1 st paragraph)
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias
		Page 14: DISCUSSION (6 th Paragraph)
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
<u> </u>		Pages 11-13: DISCUSSION (2 nd – 5 th Paragraphs)
Generalisability	21	Discuss the generalisability (external validity) of the study results Pages 11-13: DISCUSSION (2 nd – 5 th Paragraphs)
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if
		applicable, for the original study on which the present article is based
		The present study was conducted with in-kind support from investigators and co-
		authors. The original data collection was based on support from an Institutional
		travel grant.

*Give information separately for exposed and unexposed groups.

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Association of Common Mental Disorders with Health and Healthcare Factors among Women in Rural Western India: results of a cross-sectional survey.

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Keywords: Common Mental Disorders, Health Status, Healthcare Expenditure Healthcare Behavior, Rural India, Reproductive-aged Women. Ρρτου..

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ABSTRACT

Objectives

Information about common mental disorders (CMD) is needed to guide policy and clinical interventions in lower and middle-income countries. The purpose of this study was to characterize the association of CMD with three inter-related consequences of mental disorders: health status, healthcare utilization, and healthcare expenditure among women from rural western India based on a representative, cross-sectional survey.

Setting

Surveys were conducted in the waiting area of various outpatient clinics at a tertiary care hospital and in 16 rural villages in the Anand district of Gujarat, India.

Participants

700 Gujarat-speaking women between the ages of 18-45 years who resided in the Anand district of Gujarat, India were surveyed in a quasi-randomized manner. Data from 658 were used in this analysis; 19 surveys were excluded due to incompleteness, 18 participants were excluded because they were visiting hospitalized patients, and five surveys were classified as outliers.

Primary and secondary outcomes measures

Association of CMD, ascertained using WHO's Self-Reporting Questionnaire-20 (SRQ-20) tool, with self-reported 1) number of healthcare visits in the prior year; 2) health status; and 3) portion of yearly income expended on healthcare.

Results

Overall, 155 (22.8%) participants screened positive for CMD with most (81.9%) not previously diagnosed despite contact with healthcare provider in the prior year. On adjusted analyses, positive screening for CMD was associated with worse category in self-reported health status (cumulative OR= 9.39; 95% CI: 5.97-14.76), higher portion of household income expended on healthcare (cumulative OR = 2.31; 95% CL: 1.52-3.52), and increased healthcare visits in the prior year (Incidence Rate Ratio = 1.24; 95% CI: 1.07-1.44).

Conclusions

The high prevalence of potential CMD among rural women in India that is unrecognized and associated with adverse health and financial indicators highlights the individual and public health burden of CMD.

Keywords: Common Mental Disorders, Health Status, Healthcare Expenditure Healthcare Behavior, Rural India, Reproductive-aged Women.

Strengths and limitations of this study

- Our novel dataset contains information about health status and healthcare of reproductive-aged women in rural Indian, an underserved and understudied population.
- This is the first study to report the association of screening positive for common mental disorders (CMD) with self-reported health status, healthcare expenditure, and healthcare utilization among women in rural India.
- The multivariable negative binomial and ordinal logistic regression allowed robust estimation of disease-adjusted association, which preserved the data structure of self-reported measures.
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 We are limited by our cross-section study design that limits causal interpretation. However, identification of the associations between women screening positive for CMD and healthcare related expenditure holds significance in the context of a system where the majority of healthcare costs are out of pocket and women face barriers in accessing healthcare.

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INTRODUCTION

Depression is the leading cause of total years lived with disability globally. [1,2] In developed countries, depression has been associated with lower health status, increased ambulatory and emergency hospital visits, loss in productivity, and greater healthcare costs.[3,4] Despite recent estimates suggesting that low and middle-income countries (LMIC) experience over 80% of the worldwide burden attributed to depression,[1,5] there is disproportionately limited data regarding consequences from these countries. Within LMIC, further disparities exist such that regions with a relatively greater burden of common mental disorders (CMD) remain understudied.

The majority of mental health studies in India are conducted in the progressive states of Goa or Kerala, which have high levels of female empowerment and education, important predictors of mental health.[6–8] By contrast, reproductive aged women from the state of Gujarat are three times less likely to have 10 or more years of education as those from Goa and Kerala and roughly four times more likely to be married before 18 years of age.[9] Nevertheless, mental health in Gujarat is comparatively understudied and there are reports of tremendous stigma against mental disorders among community members as well as healthcare providers, further limiting access to mental health.[10–13] Because healthcare priorities are often dictated by disease burden and its impact on individuals and their communities, information about CMD and its associated healthcare outcomes is necessary to guide prioritization of mental health programs.

The goal of this study was to determine the prevalence of CMD and characterize its association with three inter-related health factors i.e. 1) self-reported health status, 2) portion of yearly household income spent on healthcare, and 3) healthcare utilization in the previous year among

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an understudied population of women from rural western India based on a representative, crosssectional survey.

METHODS

Setting and Study Design: Data was collected through a cross-sectional survey among women currently living in rural settings in the Anand district of Gujarat, India. Trained interviewers conducted face-to-face surveys in Gujarati, the local language. Participants were recruited from two different settings: 1) Shree Krishna Hospital, a tertiary care center serving the local rural population; and 2) 16 villages within a 20-kilometer radius from the hospital. In the hospital clinic waiting areas, participants were quasi-randomly selected with interviewers by approaching every third woman in the outpatient waiting area. Interviews were conducted in the waiting area but away from participants' family members and other patients in the clinic. Prior to recruitment in the villages, the layout of each village was obtained. Every third household in each of the village's colonies was approached and the first female who encountered the interviewer was asked to participate in the study. Community interviews were conducted at participants' residences. In both settings, two research supervisors, a male and a female, ensured privacy of all participants.

Participants: Seven-hundred eligible women between the ages of 18-45 years, that could comprehend and speak Gujarati, and had a rural residence within the Anand district, consented and participated in the study. Of the 700 participants interviewed for the study, data from 658 were used in this analysis; 19 surveys were excluded due to incompleteness, 18 participants were excluded because they were visiting hospitalized relatives, and five surveys were classified as outliers due to their healthcare behavior (these participants had more than 20 clinical visits in the

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previous year due to serious health conditions) yielding an analytic sample size of 658. A study of this nature with more than 642 participants would have a priori power of 90% (α error = 0.01) to detect a difference in proportions of 50% vs 35% for two groups. Based on our understanding before we conducted the study, these proportions would be reasonable to postulate for women with and without CMD who spent a substantial part of their income on health.

Funding and Ethical Approval: The data collection was funded by an institutional travel grant by Boston University. Boston University Institutional Review Board and the Human Research Ethics Committee of HM Patel Center for Medical Care and Education reviewed the study independently and approved it.

Data Collection: The study survey was drafted in English and underwent two iterations of translation back and forth between Gujarati and English. The survey was comprised of five modules: a) health status, b) current and past medical history, c) lifestyle choices, d) healthcare seeking behavior, and e) affordability of healthcare. Five trained female interviewers piloted the survey with one volunteer, each, and conducted all interviews from October 1 – October 13, 2011. An average survey lasted 20-30 minutes.

Data Variables:

Exposure variable: Symptoms of Common Mental Disorders were s assessed using the World Health Organization (WHO) Self-Reporting Questionnaire (SRQ-20).[14] Due to the absence of validation studies for SRQ-20 use in Gujarati population, we used the threshold for a positive test from a previous study conducted in a nearby location. Participants who responded 'yes' to eight or more questions were considered to have screened positive for CMD.[15] SRQ-20

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demonstrated excellent internal reliability in our population as measured by the Kuder Richardson 20 score of 0.90.

Outcome variables:

- Health status was assessed by using the first question from the SF-12 instrument: "*In general, would you say your health is*"; possible choices were (a) Excellent, (b) Very Good, (c) Good, (d) Fair, or (e) Poor. Few participants (n=14, 2.13%) reported poor health status; therefore, we grouped self-reported fair and poor health status.
- 2) Expenditure of household income on healthcare was measured by asking participants, "What most closely estimates the portion of your yearly household income spent on healthcare?" with choices offered as (a) none, (b) less than ¹/₄, (c) ¹/₄ to less than ¹/₂, (d) ¹/₂ to ³/₄, or (e) more than ³/₄. Six participants (0.9%) reported none and 17 (2.6%) reported more than ³/₄ and thus were grouped into less than ¹/₄ and more than ¹/₂ categories, respectively.
- 3) Number of healthcare visits in the previous year was determined by participant self-report. Participants were asked to report the number of times they visited a village, public, private, ayurvedic, or homeopathic clinic/hospital in the previous year. Only twelve participants reported seeing a non-allopathic medical provider and among them, all but four, also saw an allopathic provider. Therefore, the number of healthcare visits was based on aggregate visits reported, regardless of the provider.

<u>*Confounders:*</u> Potential associations between CMD and healthcare utilization, self-reported health status, and expenditure on healthcare can be confounded by the presence of other diseases, age, marital status, income, education level, and reproductive factors (total number of

pregnancies, number of living children). Therefore, these factors were adjusted using multivariable methods. Disease burden was based on self-report of current conditions or past diagnoses of chronic diseases excluding any mental health disorders (see footnotes in Table 1 for more details). Disease burden was estimated as an aggregate grouped into four categories: no disease, one disease, two diseases, and three or more diseases. Marital status, education level, and reproductive history were based on self-report. As described elsewhere,[16] monthly household income was transformed into income/person/day values to account for variation in the household size. Daily per capita income was subsequently converted to US dollars using the average currency exchange rate from 2011, the year the study was conducted and categorized into three levels (< \$0.25, \$0.25-\$1.25, >\$1.25).

Statistical Analyses: Descriptive data analyses were performed to assess the distribution of potential confounders with respect to CMD screening status. Frequencies and percentages were calculated for categorical variables; associations with CMD screening status were assessed using chi-square test for independence of attributes or Fischer's exact test. Bivariate associations of CMD screening status with number of visits to clinic in the previous year, total number of pregnancies, and number of live births were assessed using a one-way analysis of variance test. Ordered logistic regression analyses were used to quantify the relationship of positive CMD screen with health status and household income spent on healthcare. Violations of the parallel regression assumptions were ruled out using Brant test for health status ($\chi^2 = 29.76$, df = 22; p = 0.67) and income spent on healthcare outcomes ($\chi^2 = 9.37$, df = 22; p = 0.67). The association of positive CMD screen and number healthcare visits in the previous year was evaluated using negative binomial regression modeling. A negative binomial model was selected over Poisson to account for the over dispersion in the outcome (α =0.23; χ^2 = 150.05, p < 0.001); improvement of

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model fit using zero inflated negative binomial regression was tested and ruled out using vuong test (z = 0.42, p = 0.34). Unadjusted and adjusted incidence rate ratios (IRR) were calculated and interpreted as a count multiplier for the number of healthcare visits in the previous year. All three models adjusted for number of co-morbid conditions, age, income, education, marital status, and reproductive history. Subgroup analyses to investigate differences between the hospital and community-based sample, and sensitivity analyses to examine changes in the findings based on varying thresholds (6+ to 12+) for determining whether participants had positive CMD screen were performed to check for potential sources of biases. Multiple imputation using chained equations (5 imputations, 25 burn-in iterations) was performed to impute missing values for missing covariates; the one instance of a missing outcome was not imputed. The adequacy burn-in period was assessed by examining stationarity of each chain by the end of burn-in periods from 1 to 30.

RESULTS

Table 1 presents characteristics of participants who screened positive for CMD compared with participants screening negative. Using the SRQ-20 to assess symptoms suggestive of CMD, 155 (22.8%) participants screened positive having answered yes to at least eight of 20 questions. No considerable differences were found between women recruited from the clinic or village. On average, participants reported visiting a healthcare provider more than three times in the previous year. The majority of the respondents considered their health status less than very good (i.e.; good or fair/poor), and over 60% reported spending less than a quarter of their yearly income on healthcare.

Socio-economic and reproductive factors were associated with CMD screening outcome. Increased levels of education and household income were associated with decreased likelihood of screening positive for CMD. More than four out of every five (81·3%) respondents who screened positive for CMD reported they had not been diagnosed with depression or another mental health disorder by their health care provider even though all but four of these women reported visiting a healthcare provider at least once in the past year (results not shown).

	Total CMD Screening (col %)			
	N	Positive	Negative	p
Participants (N)	658	155	503	
Location: Clinic	311	43.9	48.3	0.33
# Clinic Visits ^a (mean(sd))	3.6 (2.8)	3.2(2.5)	4.6(3.5)	$0.001^{\#}$
Health Status				
Excellent	166	1.3	32.6	< 0.001*
Very Good	95	3.9	17.7	
Good	249	34.8	38.8	
Fair/Poor	148	60.0	10.9	
HHI Spent on Healthcare ^b	1 missing			
Less than 1/4	403	36.8	68.9	< 0.001
1/4 to 1/2	184	38.0	24.9	
More than $1/2$	70	25.2	6.2	
# Diseases or Conditions ^c				
Zero	221	3.9	42.2	< 0.001*
One	155	17.4	25.8	
Two	148	28.4	20.9	
Three or more	134	50.3	11.1	
Current Depression				
Yes	34	18.7	1.0	N/A
Age (years)	2 missing			
18-25	226	28.6	36.3	0.18
26-35	249	39.6	37.5	
36-45	181	31.8	26.3	
Education	2 missing			
< 7th Grade	162	34.8	21.6	
7th - 12th Grade	356	55.5	53.9	< 0.001
> 12th Grade	138	9.7	24.5	
Marital Status	1 missing			
Single	97	8.4	16.7	0.03*
Married	541	88.3	80.5	

Divorced or Widowed	19	3.3	2.8	
Daily Income Per Person	22 missing			
< \$0.25	49	13.5	5.9	0.01
\$0.25-1.25	369	56.1	58.6	
>\$1.25	218	30.4	35.5	
# Pregnancies (mean(sd))	2.13(1.78)	2.55(1.92)	2.00(1.71)	$< 0.001^{\#}$
# Living children (mean(sd))	1.60(1.35)	1.85(1.34)	1.52(1.34)	$0.001^{\#}$

a: Number of clinic visits in the previous year based on self-report

b: Portion of yearly household-income spent on healthcare expenditure

c: Participants were asked to identify using a list of 33 non-psychiatric conditions and diseases. 22 conditions and diseases reported at least once by any participant; these were reviewed by trained clinicians to identify chronic conditions. Based on the review, an aggregate variable to represent chronic disease burden was generated; it comprised of cardiovascular problems (coronary heart disease, hypertension, positive history of heart attack or related condition), pulmonary problems (difficulty breathing, chronic allergies, asthma, or chronic bronchitis), musculoskeletal pain (chronic back problems, arthritis, difficulty opening mouth, or limited mobility due to pain), toothaches, anemia, and diabetes.

^{*} Fischer's Exact Test; [#]ANOVA

The adjusted association between CMD screening status and health status as well as portion of household income spent on healthcare is presented in Table 2. After controlling for confounders, screening positive for CMD was associated with more than an nine-fold increase in the cumulative odds of reporting a worse health status (cumulative OR (cumOR)= 9.34; 95% CI: 5.93-14.70) and a two-fold increase in the cumulative odds of reporting a higher category of income expenditure on healthcare (cumOR = 2.25; 95% CL: 1.48-3.44).

Results from negative binomial regression models are reported in Table 3. Before adjusting for confounding, screening positive for CMD was associated with a 40% increase in the number of clinical visits in the previous year (IRR = 1.41; 95% CI: 1.24-1.60). After adjusting for potential confounders, the association was attenuated but remained statistically significant (IRR = 1.22; 95%CI: 1.05-1.42)

Table 2: Ordinal Logistic Regression Models for the Association between Common Mental Disorder (CMD) and a) Self-Reported Health Status and b) Yearly Income Spent on

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	Healthcare	
	Self-Reported Health Status ^a (n = 633)	Yearly Income spent on healthcare ^b $(n = 632)$
	CumOR (95% CL)*	CumOR (95% CL)*
CMD Screen: Negative (ref)		
Positive (SRQ-20 \ge 8)	9.34 (5.93-14.70)	2.25 (1.48-3.44)
Ordered categories: a= Excell	ent, Very Good, Good, Fair/Poo	r; b = <1/4, 1/4-1/2, >1/2
	tio adjusted for non-psychiatric number of pregnancies, and num	

Table 3: Multivariable negative binomial regression m	odel estimates of count multiplier (IRR ^a)
for number of clinical visits in	the previous year.

	unadjusted	adjusted* (n=633)		
	IRR (95% CL)	IRR (95% CL)		
CMD: Negative (ref)				
Positive (SRQ-20 \ge 8)	1.41 (1.24-1.60)	1.22 (1.05-1.42)		
a: IRR = incidence rate ratio is calculated by exponentiating beta co-efficients of count models.				
IRR can be interpreted as count multipliers. For example, screening positive for CMD is				
associated with a 42% increase in the number of clinical visits in the previous in comparison to				
those who do not screen positive (unadjusted estimates)				

* adjusted for non-psychiatric comorbidities, age, income, education, marital status, total number of pregnancies, and number of living children.

Sensitivity analyses based on site of enrollment (clinic vs. village), threshold values for positive

CMD screening and missing data did not reveal any changes in direction or statistical

significance for the association of CMD screening status with health status, percentage of income

spent on healthcare expenditure, or number of clinical visits in the previous year. (Table 4).

Table 4: Results of Subgroup Analyses by Location of Survey, Sensitivity Analyses using Stricter Threshold Value for Positive CMD screening, and Imputed Dataset to Account for Missing Values					
	Self-Reported Health Status ^a	Yearly Income spent on healthcare ^b	Number of clinical visits in previous year		
	(n = 633) CumOR (95% CL)*	$\frac{(n = 632)}{CumOR (95\% CL)^*}$	(n=633) IRR (95% CL)		
Original By Location	9.34 (5.93-14.70)	2.25 (1.48-3.44)	1.22 (1.05-1.42)		

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1.21 (0.98 – 1.51) 1.25 (1.03 – 1.52)				
1.23(1.03 - 1.32)				
1.37 (1.14-1.64)				
1.23 (1.06-1.42)				
/4 , 1/4-1/2, > ¹ / ₂				
Adjusted for non-psychiatric comorbidities, age, income, education, marital status, total number of				
pregnancies, and number of living children.				

DISCUSSION

In this sample of reproductive-aged women from rural western India, approximately one out of every four participants screened positive for CMD. Despite visiting a healthcare provider at least once in the previous year, the majority reported that they had not been diagnosed with depression or other mental health disorder by their health care provider. Screening positive for CMD was associated with worse self-reported health status, a higher portion of household income expended on healthcare, and an increased number of healthcare visits. The associations found in our study were robust to subgroup, sensitivity, and missing data analysis with the exception of a stronger association between health status and CMD screening status among women interviewed in clinic in comparison to those in the village. Together, these findings underscore significant negative outcomes experienced by women of reproductive age from rural western India with symptoms suggestive of CMD.

Our findings of potentially unrecognized CMD (81·3%) is similar to the 79.0% depression prevalence reported by Kohli et al for primary care attendees from another rural region in India.[17] The high rates are likely to be driven by two main factors. First, compared to western societies, people in India are more likely to attribute mental illness to personally controllable

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factors and thus mental health in rural India is associated with a tremendous amount of stigma and social disadvantage.[10,18] Consequently, Indians may be less willing to disclose psychological symptoms. Indeed, studies have shown that most Indian patients suffering from mental disease present with somatic symptoms, which may increase the likelihood that CMD goes undetected.[19–21] Second, there is a scarcity of mental healthcare providers in India and other healthcare providers do not receive adequate mental health training.[22] Thus, in primary care settings mental illness may not be considered in the differential diagnoses, especially in the context of an atypical presentation, leading to inadequate identification of mental diseases.[23]

Our findings suggest that women screening positive for CMD had visited their providers more frequently and were more likely to spend a larger portion of their household income on healthcare. The association between CMD and healthcare cost also could be self-perpetuating. Women screening positive have considerably lower appraisal of their personal health than those who screen negative, which probably explained their seeking healthcare more often. Indian women who are suffering from mental illness are known to present to primary clinics with somatic rather than psychological symptoms, which may lead to under-diagnosis and treatment of their CMD.[24] Patients and their medical providers may continue to search for a physical cause, incurring healthcare costs and a greater number of healthcare visits, while the underlying mental illness remains unrecognized and unaddressed.[23,25]

Alternatively, it is also possible that providers may have suspected mental illness but not directly addressed it with the patient; providers may have attributed possible mental illnesses to female suppression and poverty. In such instances, providers may find themselves ill-positioned to assist

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with underlying risk factors for mental health problems. Given the study design and the data collected, it is impossible to rule out this scenario; nevertheless, it is striking that majority of women screening positive for CMD report they never received a diagnosis from a health care provider despite having reporting seen a provider at least once in the previous year.

The high prevalence of poverty in India create important barriers for recognition and treatment of CMD. Due to healthcare related costs, 63 million people in India fall below the poverty line every year.[26] This is expected to rise given the inevitable increase in the prevalence of chronic, non-communicable diseases in India, which carry a greater financial burden than communicable diseases.[27,28] Treating CMD with pharmacological and psychological therapies has been shown to reduce the economic burden of healthcare among adults.[29,30] Thus, treatment of mental illness could break this vicious cycle of poverty and CMD.[29,30] The Indian government recently proposed to revamp its mental health services through the National Mental Health Policy of India (NMHPI). NMHPI proposes to increase the number of mental healthcare providers and expand coverage from 182 to 648 districts and support 11 centers of excellence in mental health to train the next generation's mental healthcare providers.[31] Despite the laudable NMHPI proposal, the urgent needs of rural Indian women may continue to go unaddressed because the proposal may be difficult to implement due to lack of funding and a cohesive implementation plan.[32]

Integration of mental healthcare into primary care could provide a solution because women suffering from mental illness most often present to primary care settings.[33,34] The increased frequency of healthcare visits among women screening positive for CMD in our study potentially

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highlights missed opportunity for intervention. Depression screening needs to be done in conjunction with a systematic approach to ensuring adequate access to mental health assessment and care.[35] It is well-established that integrated care models, such as collaborative care, effectively integrate depression and primary care, can improve clinical outcomes, and can also be carried out by non-specialist health workers.[36,37] Such approaches have also been tested in India; Patel and colleagues tested a collaborative stepped care (CSC) model that included four levels of referral before a clinical specialist became involved in care.[38] The CSC model begins with CMD screening for adult patients that present to clinic with a village health worker, and progresses through therapeutic steps of increasing intensity including Yoga, behavioral, and pharmacologic interventions. Patients who do not respond to a less intense treatment are stepped up to a higher intensity therapeutic option. The CSC model improves in mental illness over a 6month period and holds promise as an effective mechanism to improve mental health in rural India.[39] However, the wide implementation of the CSC model in India is lacking and has been limited to Goa and South India, two regions in India that face a comparatively lower burden of mental diseases. [40,41] Despite treatment success, many collaborative care models depend on care management facets that are not reliably reimbursed and therefore their broad implementation, dissemination, and associated treatment improvement are not realized.[42] The term "voltage drop" has been used to describe the less robust results found when collaborative care approaches are implemented in low resource real-world settings. [43] Thus, there is need for cost-effective treatment plans that leverage primary care providers and staff already working in the primary care setting.

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The findings from our study must be interpreted in the context of its limitations. We identified CMD status using a validated screening questionnaire, SRQ-20, instead of a diagnostic structured clinical interview. It is possible that women who screen positive for CMD may have had sub-syndromal symptoms. However, our decision to use SRQ-20 for this study was based on sound principles: 1) The SRO-20 was developed specifically for use in global health research conducted low-resource setting. It is validated, well-accepted, and has been described as a costeffective way of measuring mental health.[15] 2) The purpose of this study was not to investigate psychiatric practice or clinical management of CMD in India but rather to understand the characteristics of women who might be suffering from mental illness, and 3) In the context of India, where mental health literacy is limited, administration of a high face-validity instrument such as SRQ-20 with yes and no responses lowers the interview-burden on participants.[14] Our data was collected through a cross-sectional survey and thus we cannot comment on the causal relationship of our findings, it is possible that women with poor appraisal of their personal health develop CMD. Presence of comorbidities among our participants was captured through selfreport and therefore is vulnerable to differential recall with CMD screen positive women potentially over-reporting their conditions. However, such misclassification would likely bias our estimates toward the null hypotheses. Our estimates of household expenditure on healthcare was based on a single question and had broad categories and therefore may lack precision; however, in the context of rural Gujarat, this instrument provides information about healthcare costs that is difficult to capture and not available in other databases.[34] Additionally, we used trained local interviewers and piloted the questionnaire to enhance cultural relevancy of the questionnaire.

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In conclusion, we found a high number of rural Indian women screening positive for CMD that was unrecognized and associated with adverse impacts on overall health and economic wellbeing. Our findings suggest that there is a need to screen, assess, and manage CMD in primary healthcare and community-based settings in India. This could, in turn, improve overall health status and reduce healthcare related economic burden.

Contributors' Statement:

Apurv Soni: Soni conceptualized, designed, and implemented the study in India. Soni carried out the initial analyses, drafted the initial manuscript, and approved the final manuscript as submitted.

Nisha Fahey: Fahey conceptualized, designed, and implemented the study in India. Fahey provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Nancy Byatt: Byatt provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Anusha Prabhakaran: Prabhakaran provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Tiffany A. Moore Simas: Moore Simas provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jagdish Vankar: Vankar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Ajay Phatak: Phatak conceptualized, designed, and implemented the study in India. Phatak provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Eileen O'Keefe: O'Keefe conceptualized and designed the study. O'Keefe provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jeroan Allison: Allison provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

 Somashekhar Nimbalkar: Nimbalkar conceptualized, designed, and implemented the study in India. Nimbalkar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Competing Interests: I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: None

Data sharing statement: No additional data are available

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	Item No	Recommendation
Title and abstract	1	(<i>a</i>) Indicate the study's design with a commonly used term in the title or the abstract Page 2: ABSTRACT (Methods)
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found
		Page 2: ABSTRACT (Methods and Results)
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported Page 3: INTRODUCTION (1 st and 2 nd Paragraph)
Objectives	3	State specific objectives, including any prespecified hypotheses
		Page 3: INTRODUCTION (3 rd Paragraph)
Methods		
Study design	4	Present key elements of study design early in the paper
		Page 5: METHODS (Setting and Study Design)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment,
		exposure, follow-up, and data collection
		Page 5: METHODS (Setting and Study Design)
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of
		participants
		Pages 6 : METHODS (Participants)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effec
		modifiers. Give diagnostic criteria, if applicable
Data aggregad/	8*	Pages 7-9 : METHODS (Data Variables)
Data sources/	8.	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is
measurement		more than one group
		Pages7-9: METHODS (Data Variables)
Bias	9	Describe any efforts to address potential sources of bias
	-	Pages 8-10: METHODS (Data Variables <i>confounders</i> , Statistical Analysis)
Study size	10	Explain how the study size was arrived at
5		Page 6: METHODS (Participants)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
		Pages 7-10 : METHODS (Data Variables confounders, Statistical Analysis)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		Pages 9-10: METHODS (Statistical Analyses)
		(b) Describe any methods used to examine subgroups and interactions
		Pages 10: METHODS (Statistical Analyses)
		(c) Explain how missing data were addressed
		Pages 10: METHODS (Statistical Analyses)
		(d) If applicable, describe analytical methods taking account of sampling strategy
		We did not use sample survey weights in our study
		(<i>e</i>) Describe any sensitivity analyses
		Pages 10: METHODS (Statistical Analyses)

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Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially
		eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
		13:a-c) All participants were interviewed once when their eligibility was examined
		prior to interview. Details regarding participant participation is provided on pages 5
		and 6: METHODS (Setting and Study Design, Data collection)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and
		information on exposures and potential confounders
		Pages 10-11: RESULTS (1 st and 2 nd paragraph; Table 1)
		(b) Indicate number of participants with missing data for each variable of interest
		Page 12: RESULTS (Table 1)
Outcome data	15*	Report numbers of outcome events or summary measures
		Page 12: RESULTS (Table 1)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
		their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included
		Pages 13-14: RESULTS (3 rd and 4 th paragraph; Tables 2 and 3)
		(b) Report category boundaries when continuous variables were categorized
		Page 12: RESULTS (Table 1)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period
		Not relevant for analyses provided
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and
		sensitivity analyses
		Pages 15-16: RESULTS
Discussion		
Key results	18	Summarise key results with reference to study objectives
		Page 16-17: DISCUSSION
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias
		Page 20-21: DISCUSSION
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Other information		
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Association of Common Mental Disorder Symptoms with Health and Healthcare Factors among Women in Rural Western India: results of a cross-sectional survey.

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ABSTRACT

Objectives

Information about common mental disorders (CMD) is needed to guide policy and clinical interventions in low and middle-income countries. The purpose of this study was to characterize the association of CMD symptoms with three inter-related health and healthcare factors among women from rural western India based on a representative, cross-sectional survey.

Setting

Surveys were conducted in the waiting area of various outpatient clinics at a tertiary care hospital and in 16 rural villages in the Anand district of Gujarat, India.

Participants

700 Gujarati-speaking women between the ages of 18-45 years who resided in the Anand district of Gujarat, India were recruited in a quasi-randomized manner.

Primary and secondary outcomes measures

CMD symptoms, ascertained using WHO's Self-Reporting Questionnaire-20 (SRQ-20) tool, were associated with self-reported 1) number of healthcare visits in the prior year; 2) health status; and 3) portion of yearly income expended on healthcare.

Results

Data from 658 were used in this analysis; 19 surveys were excluded due to incompleteness, 18 participants were excluded because they were visiting hospitalized patients, and five surveys were classified as outliers. Overall, 155 (22.8%) participants screened positive for CMD symptoms (SRQ-20 score ≥ 8) with most (81.9%) not previously diagnosed despite contact with healthcare provider in the prior year. On adjusted analyses, screening positive for CMD symptoms was associated with worse category in self-reported health status (cumulative OR= 9.39; 95% CI: 5.97-14.76), higher portion of household income expended on healthcare (cumulative OR = 2.31; 95% CL: 1.52-3.52), and increased healthcare visits in the prior year (Incidence Rate Ratio = 1.24; 95% CI: 1.07-1.44).

Conclusions

The high prevalence of potential CMD among rural women in India, which is unrecognized and associated with adverse health and financial indicators highlights the individual and public health burden of CMD.

Keywords: Common Mental Disorders, Health Status, Healthcare Expenditure Healthcare Behavior, Rural India, Reproductive-aged Women.

Strengths and limitations of this study

- Our novel dataset contains information about health status and healthcare of reproductive-aged women in rural Indian, an underserved and understudied population.
- This is the first study to report the association of screening positive for symptoms of common mental disorders (CMD) with self-reported health status, healthcare expenditure, and healthcare utilization among women in rural India.
- The multivariable negative binomial and ordinal logistic regression allowed robust estimation of disease-adjusted association, which preserved the data structure of self-reported measures.
- ctic. spenditure is costs are out of , We are limited by our cross-section study design that limits causal interpretation. However, identification of the associations between women screening positive for CMD symptoms and healthcare expenditure holds significance in the context of a system where the majority of healthcare costs are out of pocket and women face barriers in accessing healthcare.

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INTRODUCTION

Depression is the leading cause of total years lived with disability globally. [1,2] In developed countries, depression has been associated with lower health status and productivity, increased ambulatory and emergency hospital visits, and greater healthcare costs.[3,4] Despite recent estimates suggesting that low and middle-income countries (LMIC) experience over 80% of the worldwide burden attributed to depression,[1,5] there is disproportionately limited data about mental health and its related factors from these countries. Within LMIC, further disparities exist such that regions with a relatively greater burden of common mental disorders (CMD) remain understudied.

The majority of mental health studies in India are conducted in the progressive states of Goa or Kerala, which have high levels of female empowerment and education, important predictors of mental health.[6–8] By contrast, reproductive-aged women from the state of Gujarat are three times less likely to have 10 or more years of education as those from Goa and Kerala and roughly four times more likely to be married before 18 years of age.[9] Nevertheless, mental health in Gujarat is comparatively understudied and there are reports of tremendous stigma against mental disorders among community members as well as healthcare providers, further limiting access to mental health.[10–13] Because healthcare priorities are often dictated by disease burden and its impact on individuals and their communities, information about CMD and its associated healthcare outcomes is necessary to guide prioritization of mental health programs.

The goal of this study was to determine the prevalence of CMD symptoms and characterize its association with three inter-related health factors i.e. 1) self-reported health status, 2) portion of yearly household income spent on healthcare, and 3) healthcare utilization in the previous year

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among an understudied population of women from rural western India based on a representative, cross-sectional survey.

METHODS

Setting and Study Design: Data were collected through a cross-sectional survey among women living in rural settings in the Anand district of Gujarat, India. Trained interviewers conducted face-to-face surveys in Gujarati, the local language. Participants were recruited in a quasirandomized manner from two different settings: 1) Shree Krishna Hospital, a tertiary care center serving the local rural population; and 2) 16 villages within a 20-kilometer radius of the hospital. In the hospital clinic waiting areas, interviewers approached every third woman seated in the outpatient waiting area. Interviews were conducted in the waiting area but away from participants' family members and other patients in the clinic. Prior to recruitment in the villages, the layout of each village was obtained. Every third household in each of the village's colonies was approached and the first female who encountered the interviewer was asked to participate in the study. Community interviews were conducted at participants' residences. In both settings, two research supervisors, a male and a female, ensured privacy of all participants.

Participants: Seven hundred eligible women between the ages of 18-45 years who could comprehend and speak Gujarati and had a rural residence within the Anand district, consented and participated in the study. For the purpose of this study, we excluded participants who were hospitalized or visiting in-patient relatives because they might experience acute emotional distress and have unique life circumstances that are different from participants identified in the outpatient area or in the community. A study of this nature with more than 642 participants would have a priori power of 90% (α error = 0.01) to detect a difference in proportions of 50%

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vs 35% for two groups. Based on our understanding before we conducted the study, these proportions would be reasonable to postulate for women with and without CMD who spend a substantial part of their income on health.

Ethics: Consent of the participants was obtained by the trained interviewers prior to survey. Interviewers read the consent to participants in Gujarati and shared a single-page fact sheet about the study with them. Willing participants were asked to sign or initial a separate consent form that was never linked to the survey to preserve the anonymous nature of the survey. Boston University Institutional Review Board and the Human Research Ethics Committee of HM Patel Center for Medical Care and Education reviewed the study independently and approved it.

Data Sources: The data used in the study were collected as part of a broader survey comprised of five modules: a) health status, b) current and past medical history, c) lifestyle choices, d) healthcare seeking behavior, and e) affordability of healthcare. The survey was drafted in English and underwent two iterations of translation back and forth between Gujarati and English. Five trained female interviewers piloted the survey with one volunteer each and conducted all interviews from October 1 – October 13, 2011. An average survey lasted 20-30 minutes. The following variables were extracted for this study:

Exposure: CMD symptoms were assessed using the World Health Organization (WHO) Self-Reporting Questionnaire (SRQ-20).[14] Due to the absence of validation studies for SRQ-20 use in Gujarati population, we used the threshold for a positive test from a previous study conducted in a nearby location. Participants who responded 'yes' to eight or more questions were

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considered to have screened positive for CMD symptoms.[15] SRQ-20 demonstrated excellent internal reliability in our population as measured by the Kuder Richardson 20 score of 0.90.

Outcomes:

- Health status was assessed by using the first question from the SF-12 instrument: "*In general, would you say your health is*" with possible choices of (a) Excellent, (b) Very Good, (c) Good, (d) Fair, or (e) Poor.
- 2) Expenditure of household income on healthcare was measured by asking participants,
 "What most closely estimates the portion of your yearly household income spent on healthcare?" with choices offered as (a) none, (b) less than ¹/₄, (c) ¹/₄ to less than ¹/₂, (d) ¹/₂ to ³/₄, or (e) more than ³/₄.
- 3) Number of healthcare visits in the previous year was determined by participant self-report. Participants were asked to report the number of times they visited a village, public, private, ayurvedic, or homeopathic clinic/hospital in the previous year.

<u>Confounders:</u> Potential associations between CMD symptoms and healthcare utilization, selfreported health status, and expenditure on healthcare can be confounded by the presence of other diseases, age, marital status, income, education level, and reproductive factors (total number of pregnancies, number of living children). Therefore, these factors were adjusted for using multivariable methods. Disease burden was based on self-report of current conditions or past diagnoses of chronic diseases excluding any mental health disorders (see footnotes in Table 1 for more details). Disease burden was estimated as an aggregate grouped into four categories: no disease, one disease, two diseases, and three or more diseases. Marital status, education level, and reproductive history were based on self-report. As described elsewhere,[16] monthly

household income was transformed into income/person/day values to account for variation in the household size. Daily per capita income was subsequently converted to US dollars using the average currency exchange rate from 2011, the year the study was conducted and categorized into three levels (< \$0.25, \$0.25-\$1.25, >\$1.25).

All items, with the exception of SRQ-20 and SF-12, were study-specific and developed based on input from care providers and community members of these settings.

Data Management and Analyses: The paper-form surveys were entered into a database using Epi-Info software. All data entry was verified for errors by a team member different than the one performing the original data entry.

Descriptive data analyses were performed to assess the distribution of potential confounders with respect to CMD symptom screening status. Frequencies and percentages were calculated for categorical variables; associations with CMD symptom screening status were assessed using chi-square test for independence of attributes or Fischer's exact test. Bivariate associations of CMD symptom screening status with number of visits to clinic in the previous year, total number of pregnancies, and number of live births were assessed using a one-way analysis of variance test. Ordered logistic regression analyses were used to quantify the relationship of positive CMD symptom screen with health status and household income spent on healthcare. The association of positive CMD screen and number of healthcare visits in the previous year was evaluated using negative binomial regression modeling. Unadjusted and adjusted incidence rate ratios (IRR) were calculated and interpreted as a count multiplier for the number of healthcare visits in the previous year. All three models adjusted for number of co-morbid conditions, age, income, education, marital status, and reproductive history. Subgroup analyses to investigate differences between

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the hospital and community-based sample and sensitivity analyses to examine changes in the findings based on varying thresholds (6+ to 12+) for determining whether participants had positive CMD symptoms screen were performed to check for potential sources of biases. Multiple imputation using chained equations (5 imputations, 25 burn-in iterations) was performed to impute missing values for missing covariates; the one instance of a missing outcome was not imputed. The adequacy of burn-in period was assessed by examining stationarity of each chain by the end of burn-in periods from 1 to 30. All statistical analyses were performed in STATA v13.

RESULTS

Of the 700 participants interviewed for the study, 19 surveys were excluded due to incompleteness, 18 participants were excluded because they were visiting hospitalized relatives, and five surveys were classified as outliers due to their healthcare behavior (these participants had more than 20 clinical visits in the previous year due to serious health conditions) yielding an analytic sample of 658 women. Using the SRQ-20 to assess symptoms suggestive of CMD, 155 (22.8%) participants screened positive having answered yes to at least eight of 20 questions (Table 1). Only twelve participants reported seeing a non-allopathic medical provider and among them, all but four, also saw an allopathic provider. Therefore, the number of healthcare visits was based on aggregate visits reported, regardless of the provider. On average, participants (n=14, 2.13%) reported poor health status; therefore, we grouped participants who self-reported fair or poor health status into one category. The majority of the respondents considered their health status less than very good (i.e.; good or fair/poor). Over 60% of participants reported spending less than a quarter of their yearly income on healthcare; six participants (0.9%) reported

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spending none, and 17 (2.6%) reported spending more than ³/₄ of their yearly income, and thus responses were categorized into 2 groups (i.e. spending less than ¹/₄, and more than ¹/₂ of yearly income). Increased levels of education and household income were associated with decreased likelihood of screening positive for CMD symptoms.

More than four out of every five (81·3%) respondents who screened positive for CMD symptoms reported they had not been diagnosed with depression or another mental health disorder by their healthcare provider even though all but four of these women reported visiting a healthcare provider at least once in the past year (results not shown).

	Total	CMD Symptoms (col %)		
	N	Positive	Negative	p
Participants (N)	658	155	503	
Location: Clinic	311	43.9	48.3	0.33
# Clinic Visits ^a (mean(sd))	3.6 (2.8)	3.2(2.5)	4.6(3.5)	$0.001^{\#}$
Health Status				
Excellent	166	1.3	32.6	<0.001
Very Good	95	3.9	17.7	
Good	249	34.8	38.8	
Fair/Poor	148	60.0	10.9	
HHI Spent on Healthcare ^b	1 missing			
Less than 1/4	403	36.8	68.9	< 0.001
1/4 to 1/2	184	38.0	24.9	
More than $1/2$	70	25.2	6.2	
# Diseases or Conditions ^c				
Zero	221	3.9	42.2	< 0.001
One	155	17.4	25.8	
Two	148	28.4	20.9	
Three or more	134	50.3	11.1	
Current Depression				
Yes	34	18.7	1.0	N/A
Age (years)	2 missing			
18-25	226	28.6	36.3	0.18

26-35	249	39.6	37.5	
36-45	181	31.8	26.3	
Education	2 missing			
< 7th Grade	162	34.8	21.6	
7th - 12th Grade	356	55.5	53.9	< 0.001
> 12th Grade	138	9.7	24.5	
Marital Status	1 missing			
Single	97	8.4	16.7	0.03*
Married	541	88.3	80.5	
Divorced or Widowed	19	3.3	2.8	
Daily Income Per Person	22 missing			
< \$0.25	49	13.5	5.9	0.01
\$0.25-1.25	369	56.1	58.6	
>\$1.25	218	30.4	35.5	
<pre># Pregnancies (mean(sd))</pre>	2.13(1.78)	2.55(1.92)	2.00(1.71)	< 0.001#
# Living children (mean(sd))	1.60(1.35)	1.85(1.34)	1.52(1.34)	0.001#
	• 1 1	10		

a: Number of clinic visits in the previous year based on self-report

b: Portion of yearly household-income spent on healthcare expenditure

c: Participants were asked to identify using a list of 33 non-psychiatric conditions and diseases. 22 conditions and diseases reported at least once by any participant; these were reviewed by trained clinicians to identify chronic conditions. Based on the review, an aggregate variable to represent chronic disease burden was generated; it comprised of cardiovascular problems (coronary heart disease, hypertension, positive history of heart attack or related condition), pulmonary problems (difficulty breathing, chronic allergies, asthma, or chronic bronchitis), musculoskeletal pain (chronic back problems, arthritis, difficulty opening mouth, or limited mobility due to pain), toothaches, anemia, and diabetes.

Fischer's Exact Test; [#]ANOVA

After controlling for confounders, screening positive for CMD symptoms was associated with more than an nine-fold increase in the cumulative odds of reporting a worse health status (cumulative OR (cumOR)= 9.34; 95% CI: 5.93-14.70) and a two-fold increase in the cumulative odds of reporting a higher category of income expenditure on healthcare (cumOR = 2.25; 95% CL: 1.48-3.44) (Table 2). Increasing number of comorbid non-psychiatric conditions were associated with self-report of lower health status and greater portion of income spent on healthcare (Supplementary Table 1). In comparison to participants with no comorbid non-psychiatric conditions, participants who reported three or more had more than twice the

cumulative odds of reporting a poorer health status (cumOR = 2.61; 95% CL: 1.60-4.24) and more than three times greater cumulative odds of spending a higher portion of their yearly income on healthcare (OR = 3.46; 95% CL 2.05 – 5.84). Violations of the parallel regression assumptions for ordered logistic regression were ruled out using Brant test for health status (χ^2 = 29.76, df = 22; p = 0.67) and income spent on healthcare outcomes (χ^2 = 9.37, df = 22; p = 0.67).

Table 2: Ordinal Logistic Regression Models for the Association between Common Mental				
Disorders (CMD) symptoms and a) Self-Reported Health Status and b) Yearly Income Spent				
on Healthcare				
	Self-Reported	Yearly Income Spent on		
	Health Status ^a $(n = 633)$	Healthcare ^b ($n = 632$)		
	CumOR (95% CL)*	CumOR (95% CL)*		
CMD Symptoms: Negative				
(ref)				
Positive (SRQ-20 \ge 8)	9.34 (5.93-14.70)	2.25 (1.48-3.44)		
Ordered categories: a= Excellent, Very Good, Good, Fair/Poor; $b = <1/4$, $1/4-1/2$, $> 1/2$				
*CumOR: Cumulative odds ratio adjusted for non-psychiatric comorbidities, age, income,				
education, marital status, total number of pregnancies, and number of living children.				

Results from negative binomial regression models are reported in Table 3. A negative binomial model was selected over Poisson to account for the over dispersion in the outcome (α =0.23; χ^2 = 150.05, p < 0.001); improvement of model fit using zero inflated negative binomial regression was tested and ruled out using Vuong Test (z = 0.42, p = 0.34). Before adjusting for confounding, screening positive for CMD symptoms was associated with a 40% increase in the number of clinical visits in the previous year (IRR = 1.41; 95% CI: 1.24-1.60). After adjusting for potential confounders, the association was attenuated but remained statistically significant (IRR = 1.22; 95% CI: 1.05-1.42). Adjusted analyses revealed that in comparison to participants with no comorbidities, women who reported experiencing multiple non-psychiatric comorbidities

were more likely to have greater number of clinic visits in the previous year (two diseases: IRR =

1.18 [1.00 -1.39]; three or more diseases: IRR = 1.27 [1.06-1.52]) (Supplementary Table 2).

Table 3: Multivariable Negative Binomial Regression Model Estimates of Count Multiplier (IRR^A) for Clinical Visits in the Previous Year Based on Screening Status for CMD Symptoms

	unadjusted	adjusted* (n=633)		
	IRR (95% CL)	IRR (95% CL)		
CMD Symptoms: Negative				
(ref)				
Positive (SRQ-20 \ge 8)	1.41 (1.24-1.60)	1.22 (1.05-1.42)		
a: IRR = incidence rate ratio is calculated by exponentiating beta co-efficients of count models.				
IRR can be interpreted as count multipliers. For example, screening positive for CMD				
symptoms is associated with a 42% increase in the number of clinical visits in the previous in				
comparison to those who do not screen positive (unadjusted estimates)				
* adjusted for non-psychiatric comorbidities, age, income, education, marital status, total				
number of pregnancies, and number of living children.				

Sensitivity analyses based on site of enrollment (clinic vs. village), threshold values for positive

screening for CMD symptoms and missing data did not reveal any changes in direction or

statistical significance for the association of CMD symptoms with health status, percentage of

income spent on healthcare expenditure, or number of clinical visits in the previous year (Table

4).

Table 4: Results of Subgroup Analyses by Location of Survey, Sensitivity Analyses using Stricter Threshold Value for Positive Screening for CMD Symptoms, and Imputed Dataset to Account for Missing Values

IVIISSING Values				
	Self-Reported Health Status ^a	Yearly Income spent on healthcare ^b	Number of clinical visits in previous year	
	(n = 633)	(n = 632)	(n=633)	
-	CumOR (95% CL)*	CumOR (95% CL)*	IRR (95% CL)	
Original	9.34 (5.93-14.70)	2.25 (1.48-3.44)	1.22 (1.05-1.42)	
By Location				
Clinic	11.79 (5.94-23.40)	2.77 (1.46-5.24)	1.21 (0.98 – 1.51)	
Village	7.72 (4.14-14.37)	2.04 (1.14-3.65)	1.25 (1.03 – 1.52)	
Threshold Value				
SRQ-20 ≥ 12	6.82 (3.72-12.51)	3.37 (1.98-5.75)	1.37 (1.14-1.64)	
Missing Data				
Imputed Dataset	8.42 (5.44-13.05)	2.23 (1.48-3.36)	1.23 (1.06-1.42)	

Ordered categories: a= Excellent, Very Good, Good, Fair/Poor; b = <1/4, 1/4-1/2, $> \frac{1}{2}$ Adjusted for non-psychiatric comorbidities, age, income, education, marital status, total number of pregnancies, and number of living children.

DISCUSSION

 In this sample of reproductive-aged women from rural western India, approximately one out of every four participants screened positive for CMD symptoms. High mental distress in this population may be attributed to overall circumstances of women's lives in this setting. We have previously reported that CMD symptoms in this setting are closely associated with poor socioeconomic status, food insecurity, and exposure to traumatic events.[17] Despite visiting a healthcare provider at least once in the previous year, the majority of participants reported that they had not been diagnosed with depression or other mental health disorder by their healthcare provider. Screening positive for CMD symptoms was associated with worse self-reported health status, a higher portion of household income expended on healthcare, and an increased number of healthcare visits. The associations found in our study were robust to subgroup, sensitivity, and missing data analysis with the exception of a stronger association between health status and CMD symptoms among women interviewed in clinic compared to those interviewed in the village.

Our finding of potentially unrecognized CMD (81·3%) is similar to the 79.0% depression prevalence reported by Kohli et al for primary care attendees from another rural region in India.[18] The high rates are likely to be driven by two main factors. First, compared to western societies, people in India are more likely to attribute mental illness to personally controllable factors and thus mental health in rural India is associated with a tremendous amount of stigma and social disadvantage.[10,19] Consequently, Indians may be less willing to disclose

psychological symptoms. Indeed, studies have shown that most Indian patients suffering from mental disease present with somatic symptoms, which may increase the likelihood that CMD goes undetected.[20–23] Second, there is a scarcity of mental healthcare providers in India and other healthcare providers do not receive adequate mental health training.[24] Thus, in primary care settings mental illness may not be considered in the differential diagnoses, especially in the context of an atypical presentation, leading to inadequate identification of mental diseases.[25]

Our findings suggest that women screening positive for CMD symptoms had visited their providers more frequently and were more likely to spend a larger portion of their household income on healthcare. The association between CMD symptoms and healthcare cost also could be self-perpetuating. Women screening positive have considerably lower appraisal of their personal health than those who screen negative, which probably explained their seeking healthcare more often. Indian women who are suffering from mental illness are known to present to primary clinics with somatic rather than psychological symptoms, which may lead to underdiagnosis and treatment of their CMD.[23] Patients and their medical providers may continue to search for a physical cause, incurring healthcare costs and a greater number of healthcare visits, while the underlying mental illness remains unrecognized and unaddressed.[25,26]

Alternatively, it is also possible that providers may have suspected mental illness but not directly addressed it with the patient; providers may have attributed possible mental illnesses to female suppression and poverty. In such instances, providers may find themselves ill-positioned to assist with underlying risk factors for mental health problems. Given the study design and the data collected, it is impossible to rule out this scenario; nevertheless, it is striking that the majority of

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women screening positive for CMD symptoms report they never received a diagnosis from a healthcare provider despite having reported seeing a provider at least once in the previous year. This represents a missed opportunity to screen and assess women for CMD. Identification of women who may have CMD or be at risk of developing CMD could facilitate detection, assessment and treatment.

The high prevalence of poverty in India creates important barriers for recognition and treatment of CMD. Due to healthcare related costs, 63 million people in India fall below the poverty line every year.[27] This number is expected to rise given the inevitable increase in the prevalence of chronic, non-communicable diseases in India, which carry a greater financial burden than communicable diseases.[28,29] Treating CMD with pharmacological and psychological therapies has been shown to reduce the economic burden of healthcare among adults.[30,31] Thus, treatment of mental illness could break this vicious cycle of poverty and CMD.[30,31] The Indian government recently proposed to revamp its mental health services through the National Mental Health Policy of India (NMHPI). NMHPI proposes to increase the number of mental healthcare providers and expand coverage from 182 to 648 districts and support 11 centers of excellence in mental health to train the next generation's mental healthcare providers.[32] Despite the laudable NMHPI proposal, the urgent needs of rural Indian women may continue to go unaddressed because the proposal may be difficult to implement due to lack of funding and a cohesive implementation plan.[33]

Integration of mental healthcare into primary care could provide a solution because women suffering from mental illness most often present to primary care settings.[34,35] The increased

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frequency of healthcare visits among women screening positive for CMD symptoms in our study potentially highlights missed opportunity for intervention. Depression screening needs to be done in conjunction with a systematic approach to ensuring adequate access to mental health assessment and care.[36] It is well-established that integrated care models, such as collaborative care, effectively integrate depression and primary care, can improve clinical outcomes, and can also be carried out by non-specialist health workers.[37,38] Such approaches have also been tested in India; Patel and colleagues tested a collaborative stepped care (CSC) model that included four levels of referral before a clinical specialist became involved in care.[39] The CSC model begins with CMD screening for adult patients that present to clinic with a village health worker, and progresses through therapeutic steps of increasing intensity including yoga, behavioral, and pharmacologic interventions. Patients who do not respond to a less intense treatment are stepped up to a higher intensity therapeutic option. The CSC model improves mental illness over a six month period and holds promise as an effective mechanism to improve mental health in rural India. [40] However, the wide implementation of the CSC model in India is lacking and has been limited to Goa and South India, two regions in India that face a comparatively lower burden of mental diseases. [41,42] Thus, there is need for cost-effective treatment plans that leverage primary care providers and staff already working in the primary care setting.

The findings from our study must be interpreted in the context of its limitations. We identified CMD symptoms using a validated screening questionnaire, SRQ-20, instead of a diagnostic structured clinical interview. It is possible that women who screen positive for CMD symptoms may have had sub-syndromal symptoms. However, our decision to use SRQ-20 for this study

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was based on sound principles: 1) The SRO-20 was developed specifically for use in global health research conducted low-resource setting. It is validated, well-accepted, and has been described as a cost-effective way of measuring mental health, [15] 2) The purpose of this study was not to investigate psychiatric practice or clinical management of CMD in India but rather to understand the characteristics of women who might be suffering from mental illness, and 3) In the context of India, where mental health literacy is limited, administration of a high facevalidity instrument such as SRQ-20 with yes and no responses lowers the interview-burden on participants.[14] Our data were collected through a cross-sectional survey and thus we cannot comment on the causal relationship of our findings, it is possible that women with poor appraisal of their personal health develop CMD symptoms. Presence of comorbidities among our participants was captured through self-report and therefore is vulnerable to differential recall where women with positive screen for CMD symptoms potentially over-report their conditions. However, such misclassification would likely bias our estimates toward the null hypotheses. Our estimates of household expenditure on healthcare were based on a single question and had broad categories and therefore may lack precision. However, we used trained local interviewers to pilot the question. Moreover, in the context of rural Gujarat, this instrument provides information about healthcare costs that is difficult to capture and not available in other databases.[35] Lastly, our finding of increased cumulative odds of reporting a higher portion of household expenditure on healthcare with increasing number of comorbidities suggests that our instrument performed as expected.

In conclusion, we found a high number of Indian women screening positive for CMD symptoms that was unrecognized and associated with adverse impacts on overall health and economic well-

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being. Our findings suggest that there is a need to screen, assess, and manage CMD in primary

healthcare and community-based settings in India. This could, in turn, improve overall health

status and reduce healthcare related economic burden.

Contributors' Statement:

Apurv Soni: Soni conceptualized, designed, and implemented the study in India. Soni carried out the initial analyses, drafted the initial manuscript, and approved the final manuscript as submitted.

Nisha Fahey: Fahey conceptualized, designed, and implemented the study in India. Fahey provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Nancy Byatt: Byatt provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Anusha Prabhakaran: Prabhakaran provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Tiffany A. Moore Simas: Moore Simas provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jagdish Vankar: Vankar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Ajay Phatak: Phatak conceptualized, designed, and implemented the study in India. Phatak provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Eileen O'Keefe: O'Keefe conceptualized and designed the study. O'Keefe provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jeroan Allison: Allison provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Somashekhar Nimbalkar: Nimbalkar conceptualized, designed, and implemented the study in India. Nimbalkar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

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Competing Interests: I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: None

Data sharing statement: No additional data are available

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Supplementary Table 1: Ordinal Logistic Regression Models for the Association between				
Chronic Co-morbid Conditions and a) Self-Reported Health Status and b) Yearly Income				
Spent on Healthcare				
	Self-Reported	Yearly Income Spent on		
	Health Status ^a $(n = 633)$	Healthcare ^b $(n = 632)$		
	CumOR (95% CL)*	CumOR (95% CL)*		
Disease or Conditions: Zero				
(ref)				
One	1.19 (0.80-1.77)	1.26 (0.76-2.07)		
Two	1.64 (1.08-2.47)	3.07 (1.90-4.96)		
Three or More	2.61 (1.60-4.24)	3.46 (2.05-5.84)		
Ordered categories: a= Excellent, Very Good, Good, Fair/Poor; $b = \langle 1/4, 1/4 - 1/2, \rangle 1/2$				
*CumOR: Cumulative odds ratio adjusted for non-psychiatric comorbidities, age, income,				
education, marital status, total number of pregnancies, and number of living children.				

Supplementary Table 2: Multivariable Negative Binomial Regression Model Estimates of
Count Multiplier (IRR ^A) for Clinical Visits in the Previous Year Based on Number of Chronic
Co-morbid Conditions

	co morora conartions	
	unadjusted	adjusted* (n=633)
	IRR (95% CL)	IRR (95% CL)
Comorbid Conidtions: None		
(ref)		
1	1.10 (0.94-1.28)	1.11 (0.95-1.29)
2	1.25 (1.07-1.46)	1.18 (1.00-1.39)
3 or more	1.47 (1.26-1.72)	1.27 (1.06-1.52)
a: IRR = incidence rate ratio is calc	culated by exponentiating b	eta co-efficients of count models.

a: IRR = incidence rate ratio is calculated by exponentiating beta co-efficients of count models. IRR can be interpreted as count multipliers. For example, screening positive for CMD symptoms is associated with a 42% increase in the number of clinical visits in the previous in comparison to those who do not screen positive (unadjusted estimates) * adjusted for non-psychiatric comorbidities, age, income, education, marital status, total number of pregnancies, and number of living children.

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstra
The and abstract	1	Page 2: ABSTRACT (Methods)
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
		Page 2: ABSTRACT (Methods and Results)
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
		Page 3: INTRODUCTION (1 st and 2 nd Paragraph)
Objectives	3	State specific objectives, including any prespecified hypotheses
		Page 3: INTRODUCTION (3 rd Paragraph)
Methods	\mathbf{O}	
Study design	4	Present key elements of study design early in the paper
Study design		Page 5: METHODS (Setting and Study Design)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment
	-	exposure, follow-up, and data collection
		Page 5: METHODS (Setting and Study Design)
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of
1		participants
		Pages 6 : METHODS (Participants)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effe
		modifiers. Give diagnostic criteria, if applicable
		Pages 7-9 : METHODS (Data Variables)
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there
		more than one group
		Pages7-9: METHODS (Data Variables)
Bias	9	Describe any efforts to address potential sources of bias
		Pages 8-10: METHODS (Data Variables confounders, Statistical Analysis)
Study size	10	Explain how the study size was arrived at
		Page 6: METHODS (Participants)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
		Pages 7-10 : METHODS (Data Variables confounders, Statistical Analysis)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confoundin
		Pages 9-10: METHODS (Statistical Analyses)
		(b) Describe any methods used to examine subgroups and interactions
		Pages 10: METHODS (Statistical Analyses)
		(c) Explain how missing data were addressed
		Pages 10: METHODS (Statistical Analyses)
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy
		We did not use sample survey weights in our study
		(\underline{e}) Describe any sensitivity analyses
		Pages 10: METHODS (Statistical Analyses)

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Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially
		eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
		13:a-c) All participants were interviewed once when their eligibility was examined
		prior to interview. Details regarding participant participation is provided on pages 5
		and 6 : METHODS (Setting and Study Design, Data collection)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and
Descriptive dutu		information on exposures and potential confounders
		Pages 10-11: RESULTS (1^{st} and 2^{nd} paragraph; Table 1)
		(b) Indicate number of participants with missing data for each variable of interest
		Page 12: RESULTS (Table 1)
Outcome data	15*	Report numbers of outcome events or summary measures
Outcome data	15	Page 12: RESULTS (Table 1)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
Wall results	10	their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included
		Pages 13-14: RESULTS (3 rd and 4 th paragraph; Tables 2 and 3)
		(b) Report category boundaries when continuous variables were categorized
		Page 12: RESULTS (Table 1)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period
		Not relevant for analyses provided
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and
,		sensitivity analyses
		Pages 15-16: RESULTS
Discussion		
Key results	18	Summarise key results with reference to study objectives
		Page 16-17: DISCUSSION
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias
		Page 20-21: DISCUSSION
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
		Pages 17-20: DISCUSSION
Generalisability	21	Discuss the generalisability (external validity) of the study results
2		Pages 17-20: DISCUSSION
Other information		-
Funding	22	Give the source of funding and the role of the funders for the present study and, if
5		applicable, for the original study on which the present article is based
		Pages 6: METHODS (Funding and Ethical Approval)

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Association of Common Mental Disorder Symptoms with Health and Healthcare Factors among Women in Rural Western India: results of a cross-sectional survey.

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Primary Subject Heading :	Global health	
Secondary Subject Heading:	Mental health, Public health, Health policy, Epidemiology	
Keywords:	MENTAL HEALTH, PUBLIC HEALTH, EPIDEMIOLOGY	
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Association of Common Mental Disorder Symptoms with Health and Healthcare Factors among Women in Rural Western India: results of a cross-sectional survey.

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Keywords: Common Mental Disorders, Health Status, Healthcare Expenditure, Healthcare Behavior, Rural India, Reproductive-aged Women.

Word Count: 3,631

References: 42

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ABSTRACT

Objectives

Information about common mental disorders (CMD) is needed to guide policy and clinical interventions in low and middle-income countries. This study's purpose was to characterize the association of CMD symptoms with three inter-related health and healthcare factors among women from rural western India based on a representative, cross-sectional survey.

Setting

Surveys were conducted in the waiting area of various outpatient clinics at a tertiary care hospital and in 16 rural villages in the Anand district of Gujarat, India.

Participants

700 Gujarati-speaking women between the ages of 18-45 years who resided in the Anand district of Gujarat, India were recruited in a quasi-randomized manner.

Primary and secondary outcomes measures

CMD symptoms, ascertained using WHO's Self-Reporting Questionnaire-20 (SRQ-20), were associated with self-reported 1) number of healthcare visits in the prior year; 2) health status; and 3) portion of yearly income expended on healthcare.

Results

Data from 658 participants were used in this analysis; 19 surveys were excluded due to incompleteness, 18 surveys were excluded because the participants were visiting hospitalized patients, and five surveys were classified as outliers. Overall, 155 (22.8%) participants screened positive for CMD symptoms (SRQ-20 score \geq 8) with most (81.9%) not previously diagnosed despite contact with healthcare provider in the prior year. On adjusted analyses, screening positive for CMD symptoms was associated with worse category in self-reported health status (cumulative OR= 9.39; 95% CI: 5.97-14.76), higher portion of household income expended on healthcare (cumulative OR = 2.31; 95% CL: 1.52-3.52), and increased healthcare visits in the prior year (Incidence Rate Ratio = 1.24; 95% CI: 1.07-1.44).

Conclusions

The high prevalence of potential CMD among women in rural India that is unrecognized and associated with adverse health and financial indicators highlights the individual and public health burden of CMD.

Keywords: Common Mental Disorders, Health Status, Healthcare Expenditure, Healthcare Behavior, Rural India, Reproductive-aged Women.

Strengths and limitations of this study

- Our novel dataset contains information about health status and healthcare utilization of reproductive-aged women in rural India, an underserved and understudied population.
- This is the first study to report the association of screening positive for symptoms of common mental disorders (CMD) with self-reported health status, healthcare expenditure, and healthcare utilization among women in rural India.
- The multivariable negative binomial and ordinal logistic regression allowed robust estimation of disease-adjusted association, which preserved the data structure of self-reported measures.
- ctio. geassoci. costs are out of . We are limited by our cross-sectional study design that limits causal interpretation. However, identification of the associations between women screening positive for CMD symptoms and healthcare expenditure holds significance in the context of a system where the majority of healthcare costs are out of pocket and women face barriers in accessing healthcare.

INTRODUCTION

Depression is the leading cause of total years lived with disability globally. [1,2] In developed countries, depression has been associated with lower health status and productivity, increased ambulatory and emergency hospital visits, and greater healthcare costs.[3,4] Despite recent estimates suggesting that low and middle-income countries (LMIC) experience over 80% of the worldwide burden attributed to depression,[1,5] there is disproportionately limited data about mental health and its related factors from these countries. Within LMIC, further disparities exist such that regions with a relatively greater burden of common mental disorders (CMD) remain understudied.

The majority of mental health studies in India are conducted in the progressive states of Goa and Kerala, which have high levels of female empowerment and education, important predictors of mental health.[6–8] By contrast, reproductive-aged women from the state of Gujarat are three times less likely to have 10 or more years of education compared to those from Goa and Kerala and roughly four times more likely to be married before 18 years of age.[9] Nevertheless, mental health in Gujarat is comparatively understudied and there are reports of tremendous stigma against mental disorders among community members as well as healthcare providers, which further limits access to mental health care.[10–13] Because healthcare priorities are often dictated by disease burden and its impact on individuals and their communities, information about CMD and its associated healthcare outcomes is necessary to guide prioritization of mental health programs.

The goal of this study was to determine the prevalence of CMD symptoms and characterize its association with three inter-related health factors i.e. 1) self-reported health status, 2) portion of

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METHODS

Setting and Study Design: Data were collected through a cross-sectional survey among women living in rural settings in the Anand district of Gujarat, India. Trained interviewers conducted face-to-face surveys in Gujarati, the local language. Participants were recruited in a quasirandomized manner from two different settings: 1) Shree Krishna Hospital, a tertiary care center serving the local rural population; and 2) 16 villages within a 20-kilometer radius of the hospital. In the hospital clinic waiting areas, interviewers approached every third woman seated in the outpatient waiting area. Interviews were conducted in the waiting area but away from participants' family members and other patients in the clinic. Prior to recruitment in the villages, the layout of each village was obtained. Every third household in each of the village's colonies was approached and the first female who encountered the interviewer was asked to participate in the study. Community interviews were conducted at participants' residences. In both settings, two research supervisors, a male and a female, ensured privacy of all participants.

Participants: Seven hundred eligible women between the ages of 18-45 years who could comprehend and speak Gujarati and had a rural residence within the Anand district consented and participated in the study. For the purpose of this study, we excluded participants who were hospitalized or visiting in-patient relatives because they might experience acute emotional distress and have unique life circumstances that are different from participants identified in the outpatient area or in the community. A study of this nature with more than 642 participants

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would have a priori power of 90% (α error = 0.01) to detect a difference in proportions of 50% vs 35% for two groups. Based on our understanding before we conducted the study, these proportions would be reasonable to postulate for women with and without CMD who spend a substantial part of their income on health.

Ethics: Consent of the participants was obtained by trained interviewers prior to survey. Interviewers read the consent to participants in Gujarati and shared a single-page fact sheet about the study with them. Willing participants were asked to sign or initial a separate consent form that was never linked to the survey to preserve the anonymous nature of the survey. Boston University Institutional Review Board and the Human Research Ethics Committee of HM Patel Center for Medical Care and Education reviewed the study independently and approved it.

Data Sources: The data used in the study were collected as part of a broader survey comprised of five modules: a) health status, b) current and past medical history, c) lifestyle choices, d) healthcare seeking behavior, and e) affordability of healthcare. The survey was drafted in English and underwent two iterations of translation back and forth between Gujarati and English. Five trained female interviewers piloted the survey with one volunteer each and then conducted all interviews from October 1 – October 13, 2011. An average survey lasted 20-30 minutes. The following variables were extracted for this study:

Exposure: CMD symptoms were assessed using the World Health Organization (WHO) Self-Reporting Questionnaire (SRQ-20).[14] Due to the absence of validation studies for SRQ-20 use in Gujarati population, we used the threshold for a positive test from a previous study conducted in a nearby location. Participants who responded 'yes' to eight or more questions were

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considered to have screened positive for CMD symptoms.[15] SRQ-20 demonstrated excellent internal reliability in our population as measured by the Kuder Richardson 20 score of 0.90.

Outcomes:

- Health status was assessed by using the first question from the SF-12 instrument: "*In general, would you say your health is*" with possible choices of (a) Excellent, (b) Very Good, (c) Good, (d) Fair, or (e) Poor.
- 2) Expenditure of household income on healthcare was measured by asking participants,
 "What most closely estimates the portion of your yearly household income spent on healthcare?" with choices offered as (a) None, (b) Less than ¹/₄, (c) ¹/₄ to less than ¹/₂, (d) ¹/₂ to ³/₄, or (e) More than ³/₄.
- Number of healthcare visits in the previous year was determined by participant selfreport. Participants were asked to report the number of times they visited a village, public, private, ayurvedic, or homeopathic clinic/hospital in the previous year.

<u>Confounders:</u> Potential associations between CMD symptoms and healthcare utilization, selfreported health status, and expenditure on healthcare can be confounded by the presence of other diseases, age, marital status, income, education level, and reproductive factors (total number of pregnancies, number of living children). Therefore, these factors were adjusted for using multivariable methods. Disease burden was based on self-report of current conditions or past diagnoses of chronic diseases excluding any mental health disorders (see footnotes in Table 1 for more details). Disease burden was estimated as an aggregate grouped into four categories: no disease, one disease, two diseases, and three or more diseases. Marital status, education level, and reproductive history were based on self-report. As described elsewhere,[16] monthly

household income was transformed into income/person/day values to account for variation in the household size. Daily per capita income was subsequently converted to US dollars using the average currency exchange rate from 2011, the year the study was conducted and categorized into three levels (< \$0.25, \$0.25-\$1.25, >\$1.25).

All items, with the exception of SRQ-20 and SF-12, were study-specific and developed based on input from care providers and community members of these settings.

Data Management and Analyses: The paper-form surveys were entered into a database using Epi-Info software. All data entry was verified for errors by a team member different than the one performing the original data entry.

Descriptive data analyses were performed to assess the distribution of potential confounders with respect to CMD symptom screening status. Frequencies and percentages were calculated for categorical variables; associations with CMD symptom screening status were assessed using chi-square test for independence of attributes or Fischer's exact test. Bivariate associations of CMD symptom screening status with number of visits to clinic in the previous year, total number of pregnancies, and number of live births were assessed using a one-way analysis of variance test. Ordered logistic regression analyses were used to quantify the relationship of positive CMD symptom screen with health status and household income spent on healthcare. The association of positive CMD screen and number of healthcare visits in the previous year was evaluated using negative binomial regression modeling. Unadjusted and adjusted incidence rate ratios (IRR) were calculated and interpreted as a count multiplier for the number of healthcare visits in the previous year. All three models adjusted for number of co-morbid conditions, age, income, education, marital status, and reproductive history. Subgroup analyses to investigate differences between

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the hospital and community-based sample and sensitivity analyses to examine changes in the findings based on varying thresholds (6+ to 12+) for determining whether participants had positive CMD symptoms screen were performed to check for potential sources of biases. Multiple imputation using chained equations (5 imputations, 25 burn-in iterations) was performed to impute missing values for missing covariates; the one instance of a missing outcome was not imputed. The adequacy of burn-in period was assessed by examining stationarity of each chain by the end of burn-in periods from 1 to 30. All statistical analyses were performed in STATA v13.

RESULTS

Of the 700 participants interviewed for the study, 19 surveys were excluded due to incompleteness, 18 participants were excluded because they were visiting hospitalized relatives, and five surveys were classified as outliers due to their healthcare behavior (these participants were identified using univariate distribution of healthcare visits because they had more than 20 clinical visits in the previous year due to serious health conditions) yielding an analytic sample of 658 women. Using the SRQ-20 to assess symptoms suggestive of CMD, 155 (22.8%) participants screened positive having answered yes to at least eight of 20 questions (Table 1). Only twelve participants reported seeing a non-allopathic medical provider and among them, all but four also saw an allopathic provider. Therefore, the number of healthcare visits was based on aggregate visits reported, regardless of the provider. On average, participants reported visiting a healthcare provider more than three times in the previous year. Few participants (n=14, 2.13%) reported poor health status; therefore, we grouped participants who self-reported fair or poor health status into one category. The majority of the respondents considered their health status less than very good (i.e.; good or fair/poor). Over 60% of participants reported spending less than

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a quarter of their yearly income on healthcare; six participants (0.9%) reported spending none, and 17 (2.6%) reported spending more than ³/₄ of their yearly income, and thus responses were categorized into 2 groups (i.e. spending less than ¹/₄ and more than ¹/₂ of yearly income). Increased levels of education and household income were associated with decreased likelihood of screening positive for CMD symptoms.

More than four out of every five $(81\cdot3\%)$ respondents who screened positive for CMD symptoms reported they had not been diagnosed with depression or another mental health disorder by their healthcare provider even though all but four of these women reported visiting a healthcare provider at least once in the past year (results not shown).

	Total	CMD Symptoms (col %)		
	Ν	Positive	Negative	p
Participants (N)	658	155	503	
Location: Clinic	311	43.9	48.3	0.33
# Clinic Visits ^a (mean(sd))	3.6 (2.8)	3.2(2.5)	4.6(3.5)	$0.001^{\#}$
Health Status				
Excellent	166	1.3	32.6	< 0.001*
Very Good	95	3.9	17.7	
Good	249	34.8	38.8	
Fair/Poor	148	60.0	10.9	
HHI Spent on Healthcare ^b	1 missing			
Less than 1/4	403	36.8	68.9	< 0.001
1/4 to 1/2	184	38.0	24.9	
More than $1/2$	70	25.2	6.2	
# Diseases or Conditions ^c				
Zero	221	3.9	42.2	< 0.001*
One	155	17.4	25.8	
Two	148	28.4	20.9	
Three or more	134	50.3	11.1	
Current Depression				
Yes	34	18.7	1.0	N/A
Age (years)	2 missing			

18-25	226	28.6	36.3	0.18
26-35	249	39.6	37.5	
36-45	181	31.8	26.3	
Education	2 missing			
< 7th Grade	162	34.8	21.6	0.001
7th - 12th Grade	356	55.5	53.9	< 0.001
> 12th Grade	138	9.7	24.5	
Marital Status	1 missing			
Single	97	8.4	16.7	0.03*
Married	541	88.3	80.5	
Divorced or Widowed	19	3.3	2.8	
Daily Income Per Person	22 missing			
< \$0.25	49	13.5	5.9	0.01
\$0.25-1.25	369	56.1	58.6	
>\$1.25	218	30.4	35.5	
# Pregnancies (mean(sd))	2.13(1.78)	2.55(1.92)	2.00(1.71)	< 0.001 #
<pre># Living children (mean(sd))</pre>	1.60(1.35)	1.85(1.34)	1.52(1.34)	$0.001^{\#}$

a: Number of clinic visits in the previous year based on self-report

b: Portion of yearly household-income spent on healthcare expenditure

c: Participants were asked to identify using a list of 33 non-psychiatric conditions and diseases. 22 conditions and diseases reported at least once by any participant; these were reviewed by trained clinicians to identify chronic conditions. Based on the review, an aggregate variable to represent chronic disease burden was generated; it comprised of cardiovascular problems (coronary heart disease, hypertension, positive history of heart attack or related condition), pulmonary problems (difficulty breathing, chronic allergies, asthma, or chronic bronchitis), musculoskeletal pain (chronic back problems, arthritis, difficulty opening mouth, or limited mobility due to pain), toothaches, anemia, and diabetes.

Fischer's Exact Test; [#]ANOVA

After controlling for confounders, screening positive for CMD symptoms was associated with

more than an nine-fold increase in the cumulative odds of reporting a worse health status

(cumulative OR (cumOR)= 9.34; 95% CI: 5.93-14.70) and a two-fold increase in the cumulative

odds of reporting a higher category of income expenditure on healthcare (cumOR = 2.25; 95%

CL: 1.48-3.44) (Table 2). Increasing number of comorbid non-psychiatric conditions were

associated with self-report of lower health status and greater portion of income spent on

healthcare (Supplementary Table 1). In comparison to participants with no comorbid non-

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psychiatric conditions, participants who reported three or more had more than twice the cumulative odds of reporting a poorer health status (cumOR = 2.61; 95% CL: 1.60-4.24) and more than three times greater cumulative odds of spending a higher portion of their yearly income on healthcare (OR = 3.46; 95% CL 2.05 – 5.84). Violations of the parallel regression assumptions for ordered logistic regression were ruled out using Brant test for health status (χ^2 = 29.76, df = 22; p = 0.67) and income spent on healthcare outcomes (χ^2 = 9.37, df = 22; p = 0.67).

Table 2: Ordinal Logistic Regr		
Disorders (CMD) Symptoms an	, I	us and b) Yearly Income Spent
	on Healthcare	
	Self-Reported	Yearly Income Spent on
	Health Status ^{a} (n = 633)	Healthcare ^b ($n = 632$)
	CumOR (95% CL)*	CumOR (95% CL)*
CMD Symptoms: Negative		
(ref)		
Positive (SRQ-20 \ge 8)	9.34 (5.93-14.70)	2.25 (1.48-3.44)
Ordered categories: a= Exceller	t, Very Good, Good, Fair/Poo	r; b = $<1/4$, $1/4-1/2$, $>1/2$
*CumOR: Cumulative odds ratio	adjusted for non-psychiatric	comorbidities, age, income,
education, marital status, total nu	umber of pregnancies, and nun	nber of living children.

Results from negative binomial regression models are reported in Table 3. A negative binomial model was selected over Poisson to account for the over dispersion in the outcome (α =0.23; χ^2 = 150.05, p < 0.001); improvement of model fit using zero inflated negative binomial regression was tested and ruled out using Vuong Test (z = 0.42, p = 0.34). Before adjusting for confounding, screening positive for CMD symptoms was associated with a 40% increase in the number of clinical visits in the previous year (IRR = 1.41; 95% CI: 1.24-1.60). After adjusting for potential confounders, the association was attenuated but remained statistically significant (IRR = 1.22; 95% CI: 1.05-1.42). Adjusted analyses revealed that in comparison to participants with no comorbidities, women who reported experiencing multiple non-psychiatric comorbidities

were more likely to have greater number of clinic visits in the previous year (two diseases: IRR =

1.18 [1.00 -1.39]; three or more diseases: IRR = 1.27 [1.06-1.52]) (Supplementary Table 2).

Table 3: Multivariable Negative Binomial Regression Model Estimates of Count Multiplier (IRR^A) for Clinical Visits in the Previous Year Based on Screening Status for CMD Symptoms

	unadjusted	adjusted* (n=633)
	IRR (95% CL)	IRR (95% CL)
CMD Symptoms: Negative		
(ref)		
Positive (SRQ-20 \ge 8)	1.41 (1.24-1.60)	1.22 (1.05-1.42)
a: IRR = incidence rate ratio is cal	culated by exponentiating l	beta co-efficients of count models.
IRR can be interpreted as count m		
symptoms is associated with a 42%		1
comparison to those who do not so		
* adjusted for non-psychiatric com		ucation, marital status, total
number of pregnancies, and number	er of living children.	

Sensitivity analyses based on site of enrollment (clinic vs. village), threshold values for positive

screening for CMD symptoms and missing data did not reveal any changes in direction or

statistical significance for the association of CMD symptoms with health status, percentage of

income spent on healthcare expenditure, or number of clinical visits in the previous year (Table

4).

Table 4: Results of Subgroup Analyses by Location of Survey, Sensitivity Analyses using Stricter Threshold Value for Positive Screening for CMD Symptoms, and Imputed Dataset to Account for Missing Values

	10115	sing values	
	Self-Reported	Yearly Income spent	Number of Clinical
	Health Status ^a	on Healthcare ^b	Visits in Previous Year
_	(n = 633)	(n = 632)	(n=633)
	CumOR (95% CL)*	CumOR (95% CL)*	IRR (95% CL)
Original	9.34 (5.93-14.70)	2.25 (1.48-3.44)	1.22 (1.05-1.42)
By Location			
Clinic	11.79 (5.94-23.40)	2.77 (1.46-5.24)	1.21 (0.98 – 1.51)
Village	7.72 (4.14-14.37)	2.04 (1.14-3.65)	1.25 (1.03 – 1.52)
Threshold Value			
SRQ-20 \ge 12	6.82 (3.72-12.51)	3.37 (1.98-5.75)	1.37 (1.14-1.64)
Missing Data			
Imputed Dataset	8.42 (5.44-13.05)	2.23 (1.48-3.36)	1.23 (1.06-1.42)

Ordered categories: a= Excellent, Very Good, Good, Fair/Poor; b = <1/4, 1/4-1/2, $> \frac{1}{2}$ Adjusted for non-psychiatric comorbidities, age, income, education, marital status, total number of pregnancies, and number of living children.

DISCUSSION

 In this sample of reproductive-aged women from rural western India, approximately one out of every four participants screened positive for CMD symptoms. High mental distress in this population may be attributed to overall circumstances of women's lives in this setting. We have previously reported that CMD symptoms in this setting are closely associated with poor socioeconomic status, food insecurity, and exposure to traumatic events.[17] Despite visiting a healthcare provider at least once in the previous year, the majority of participants reported that they had not been diagnosed with depression or other mental health disorder by their healthcare provider. Screening positive for CMD symptoms was associated with worse self-reported health status, a higher portion of household income expended on healthcare, and an increased number of healthcare visits. The associations found in our study were robust to subgroup, sensitivity, and missing data analysis with the exception of a stronger association between health status and CMD symptoms among women interviewed in clinic compared to those interviewed in the village.

Our finding of potentially unrecognized CMD (81·3%) is similar to the 79.0% depression prevalence reported by Kohli et al for primary care attendees from another rural region in India.[18] The high rates are likely to be driven by two main factors. First, compared to western societies, people in India are more likely to attribute mental illness to personally controllable factors and thus mental health in rural India is associated with a tremendous amount of stigma and social disadvantage.[10,19] Consequently, Indians may be less willing to disclose

psychological symptoms. Indeed, studies have shown that most Indian patients suffering from mental disease present with somatic symptoms, which may increase the likelihood that CMD goes undetected.[20–23] Second, there is a scarcity of mental healthcare providers in India and other healthcare providers do not receive adequate mental health training.[24] Thus, in primary care settings mental illness may not be considered in the differential diagnoses, especially in the context of an atypical presentation, leading to inadequate identification of mental diseases.[25]

Our findings suggest that women screening positive for CMD symptoms had visited their providers more frequently and were more likely to spend a larger portion of their household income on healthcare. The association between CMD symptoms and healthcare cost also could be self-perpetuating. Women screening positive have considerably lower appraisal of their personal health than those who screen negative, which probably explained their seeking healthcare more often. Indian women who are suffering from mental illness are known to present to primary clinics with somatic rather than psychological symptoms, which may lead to underdiagnosis and treatment of their CMD.[23] Patients and their medical providers may continue to search for a physical cause, incurring healthcare costs and a greater number of healthcare visits, while the underlying mental illness remains unrecognized and unaddressed.[25,26]

Alternatively, it is also possible that providers may have suspected mental illness but not directly addressed it with the patient; providers may have attributed possible mental illnesses to female suppression and poverty. In such instances, providers may find themselves ill-positioned to assist with underlying risk factors for mental health problems. Given the study design and the data collected, it is impossible to rule out this scenario; nevertheless, it is striking that the majority of

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women screening positive for CMD symptoms report they never received a diagnosis from a healthcare provider despite having reported seeing a provider at least once in the previous year. This represents a missed opportunity to screen and assess women for CMD. Identification of women who may have CMD or be at risk of developing CMD could facilitate detection, assessment, and treatment.

The high prevalence of poverty in India creates important barriers for recognition and treatment of CMD. Due to healthcare related costs, 63 million people in India fall below the poverty line every year.[27] This number is expected to rise given the inevitable increase in the prevalence of chronic, non-communicable diseases in India, which carry a greater financial burden than communicable diseases.[28,29] Treating CMD with pharmacological and psychological therapies has been shown to reduce the economic burden of healthcare among adults.[30,31] Thus, treatment of mental illness could break this vicious cycle of poverty and CMD.[30,31] The Indian government recently proposed to revamp its mental health services through the National Mental Health Policy of India (NMHPI). NMHPI proposes to increase the number of mental healthcare providers and expand coverage from 182 to 648 districts and support 11 centers of excellence in mental health to train the next generation's mental healthcare providers.[32] Despite the laudable NMHPI proposal, the urgent needs of rural Indian women may continue to go unaddressed because the proposal may be difficult to implement due to lack of funding and a cohesive implementation plan.[33]

Integration of mental healthcare into primary care could provide a solution because women suffering from mental illness most often present to primary care settings.[34,35] The increased

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frequency of healthcare visits among women screening positive for CMD symptoms in our study potentially highlights missed opportunity for intervention. Depression screening needs to be done in conjunction with a systematic approach to ensuring adequate access to mental health assessment and care.[36] It is well-established that integrated care models, such as collaborative care, effectively integrate depression and primary care, can improve clinical outcomes, and can also be carried out by non-specialist health workers.[37,38] Such approaches have also been tested in India; Patel and colleagues tested a collaborative stepped care (CSC) model that included four levels of referral before a clinical specialist became involved in care.[39] The CSC model begins with CMD screening for adult patients that present to clinic with a village health worker, and progresses through therapeutic steps of increasing intensity including yoga, behavioral, and pharmacologic interventions. Patients who do not respond to a less intense treatment are stepped up to a higher intensity therapeutic option. The CSC model improves mental illness over a six month period and holds promise as an effective mechanism to improve mental health in rural India. [40] However, the wide implementation of the CSC model in India is lacking and has been limited to Goa and South India, two regions in India that face a comparatively lower burden of mental diseases. [41,42] Thus, there is need for cost-effective treatment plans that leverage primary care providers and staff already working in the primary care setting.

The findings from our study must be interpreted in the context of its limitations. We identified CMD symptoms using a validated screening questionnaire, SRQ-20, instead of a diagnostic structured clinical interview. It is possible that women who screen positive for CMD symptoms may have had sub-syndromal symptoms. However, our decision to use SRQ-20 for this study

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was based on sound principles: 1) The SRO-20 was developed specifically for use in global health research conducted in low-resource setting. It is validated, well-accepted, and has been described as a cost-effective way of measuring mental health, [15] 2) The purpose of this study was not to investigate psychiatric practice or clinical management of CMD in India but rather to understand the characteristics of women who might be suffering from mental illness, and 3) In the context of India, where mental health literacy is limited, administration of a high facevalidity instrument such as SRQ-20 with yes and no responses lowers the interview-burden on participants.[14] Our data were collected through a cross-sectional survey and thus we cannot comment on the causal relationship of our findings, it is possible that women with poor appraisal of their personal health develop CMD symptoms. Presence of comorbidities among our participants was captured through self-report and therefore is vulnerable to differential recall where women with positive screen for CMD symptoms potentially over-report their conditions. However, such misclassification would likely bias our estimates toward the null hypotheses. Our estimates of household expenditure on healthcare were based on a single question and had broad categories and therefore may lack precision. However, we used trained local interviewers to pilot the question. Moreover, in the context of rural Gujarat, this instrument provides information about healthcare costs that is difficult to capture and not available in other databases.[35] Lastly, our finding of increased cumulative odds of reporting a higher portion of household expenditure on healthcare with increasing number of comorbidities suggests that our instrument performed as expected.

In conclusion, we found a high number of Indian women screening positive for CMD symptoms that were unrecognized and associated with adverse impacts on overall health and economic

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well-being. Our findings suggest that there is a need to screen, assess, and manage CMD in

primary healthcare and community-based settings in India. This could, in turn, improve overall

health status and reduce healthcare related economic burden.

Contributors' Statement:

Apurv Soni: Soni conceptualized, designed, and implemented the study in India. Soni carried out the initial analyses, drafted the initial manuscript, and approved the final manuscript as submitted.

Nisha Fahey: Fahey conceptualized, designed, and implemented the study in India. Fahey provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Nancy Byatt: Byatt provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Anusha Prabhakaran: Prabhakaran provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Tiffany A. Moore Simas: Moore Simas provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jagdish Vankar: Vankar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Ajay Phatak: Phatak conceptualized, designed, and implemented the study in India. Phatak provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Eileen O'Keefe: O'Keefe conceptualized and designed the study. O'Keefe provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Jeroan Allison: Allison provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

Somashekhar Nimbalkar: Nimbalkar conceptualized, designed, and implemented the study in India. Nimbalkar provided input to the analyses, contributed to the drafting of the manuscript, and approved the final manuscript as submitted.

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Competing Interests: I have read and understood the BMJ Group policy on declaration of interests and declare the following interests: None

Data sharing statement: No additional data are available

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Supplementary Table 1: Ordina	6 6	
Chronic Co-morbid Conditions	s and a) Self-Reported Health	Status and b) Yearly Income
	Spent on Healthcare	
	Self-Reported	Yearly Income Spent on
	Health Status ^a $(n = 633)$	Healthcare ^b $(n = 632)$
	CumOR (95% CL)*	CumOR (95% CL)*
Disease or Conditions: Zero		
(ref)		
One	1.19 (0.80-1.77)	1.26 (0.76-2.07)
Two	1.64 (1.08-2.47)	3.07 (1.90-4.96)
Three or More	2.61 (1.60-4.24)	3.46 (2.05-5.84)
Ordered categories: a= Excellent	t, Very Good, Good, Fair/Poor	r; b = $<1/4$, $1/4-1/2$, $>1/2$
*CumOR: Cumulative odds ratio	adjusted for non-psychiatric of	comorbidities, age, income,
education, marital status, total nu	mber of pregnancies, and nun	ber of living children.

Supplementary Table 2: Multivariable Negative Binomial Regression Model Estimates of
Count Multiplier (IRR ^A) for Clinical Visits in the Previous Year Based on Number of Chronic
Co-morbid Conditions

	co morora conartions	
	unadjusted	adjusted* (n=633)
	IRR (95% CL)	IRR (95% CL)
Comorbid Conidtions: None		
(ref)		
1	1.10 (0.94-1.28)	1.11 (0.95-1.29)
2	1.25 (1.07-1.46)	1.18 (1.00-1.39)
3 or more	1.47 (1.26-1.72)	1.27 (1.06-1.52)
a: IRR = incidence rate ratio is calc	culated by exponentiating b	eta co-efficients of count models.

a: IRR = incidence rate ratio is calculated by exponentiating beta co-efficients of count models. IRR can be interpreted as count multipliers. For example, screening positive for CMD symptoms is associated with a 42% increase in the number of clinical visits in the previous in comparison to those who do not screen positive (unadjusted estimates) * adjusted for non-psychiatric comorbidities, age, income, education, marital status, total number of pregnancies, and number of living children.

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstra
The and abstract	1	Page 2: ABSTRACT (Methods)
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
		Page 2: ABSTRACT (Methods and Results)
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
		Page 3: INTRODUCTION (1 st and 2 nd Paragraph)
Objectives	3	State specific objectives, including any prespecified hypotheses
		Page 3: INTRODUCTION (3 rd Paragraph)
Methods	\mathbf{O}	
Study design	4	Present key elements of study design early in the paper
Study design		Page 5: METHODS (Setting and Study Design)
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment
	-	exposure, follow-up, and data collection
		Page 5: METHODS (Setting and Study Design)
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of
1		participants
		Pages 6 : METHODS (Participants)
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effe
		modifiers. Give diagnostic criteria, if applicable
		Pages 7-9 : METHODS (Data Variables)
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there
		more than one group
		Pages7-9: METHODS (Data Variables)
Bias	9	Describe any efforts to address potential sources of bias
		Pages 8-10: METHODS (Data Variables confounders, Statistical Analysis)
Study size	10	Explain how the study size was arrived at
		Page 6: METHODS (Participants)
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
		Pages 7-10 : METHODS (Data Variables confounders, Statistical Analysis)
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confoundin
		Pages 9-10: METHODS (Statistical Analyses)
		(b) Describe any methods used to examine subgroups and interactions
		Pages 10: METHODS (Statistical Analyses)
		(c) Explain how missing data were addressed
		Pages 10: METHODS (Statistical Analyses)
		(<i>d</i>) If applicable, describe analytical methods taking account of sampling strategy
		We did not use sample survey weights in our study
		(\underline{e}) Describe any sensitivity analyses
		Pages 10: METHODS (Statistical Analyses)

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Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially
		eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
		13:a-c) All participants were interviewed once when their eligibility was examined
		prior to interview. Details regarding participant participation is provided on pages 5
		and 6 : METHODS (Setting and Study Design, Data collection)
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and
		information on exposures and potential confounders
		Pages 10-11: RESULTS (1^{st} and 2^{nd} paragraph; Table 1)
		(b) Indicate number of participants with missing data for each variable of interest
		Page 12: RESULTS (Table 1)
Outcome data	15*	Report numbers of outcome events or summary measures
Outcome data	15	Page 12: RESULTS (Table 1)
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
wall results	10	their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included
		Pages 13-14: RESULTS (3 rd and 4 th paragraph; Tables 2 and 3)
		(b) Report category boundaries when continuous variables were categorized
		Page 12: RESULTS (Table 1)
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period
		Not relevant for analyses provided
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and
, ,		sensitivity analyses
		Pages 15-16: RESULTS
Discussion		
Key results	18	Summarise key results with reference to study objectives
		Page 16-17: DISCUSSION
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or
		imprecision. Discuss both direction and magnitude of any potential bias
		Page 20-21: DISCUSSION
Interpretation 20	20	Give a cautious overall interpretation of results considering objectives, limitations,
		multiplicity of analyses, results from similar studies, and other relevant evidence
		Pages 17-20: DISCUSSION
Generalisability	21	Discuss the generalisability (external validity) of the study results
5		Pages 17-20: DISCUSSION
Other information		-
Funding	22	Give the source of funding and the role of the funders for the present study and, if
i unum <u>b</u>		applicable, for the original study on which the present article is based
		Pages 6: METHODS (Funding and Ethical Approval)