Title :A Randomised trial of enhanced community care, in improving treatment adherence and outcome in women with common mental disorders.

Investigators

K. Srinivasan

Anton Isaacs

Deepthi N Shanbhag

Institution

St. John's Medical College and Hospital

Bangalore.

EXECUTIVE SUMMARY

Introduction:

Common mental disorders refer to depression and anxiety syndromes and are among the most important cause of psychiatric morbidity in a primary health. The prevalence of Common Mental Disorders [CMD] in primary care settings in India and other Southeast Asian countries ranges between 20 and 45%. Most patients with CMD presenting to the primary care receive inappropriate symptomatic treatment [14]. The majority of patients with CMD in India and other developing countries receive pharmacotherapy, the clinical effectiveness of which is in the main limited by two factors; patient adherence to the recommended protocol and under-diagnosis and/or sub optimal treatment by primary care doctors[22]. There have been many efforts to improve treatment adherence in patients diagnosed with depression at primary care clinics. Studies carried out in the west implementing multilevel interventions and collaborative care has shown to significantly improve treatment adherence [26] and treatment benefit [27]. There are few studies from resource poor countries on improving treatment adherence in primary care patients. A randomized controlled study from Chile using a stepped care approach, reported that 70% of adult female primary care patients in the experimental group had recovered compared with 30% of the usual care group. Our project aims at studying whether patient adherence to treatment will improve with the intervention of **Community Health Workers [CHWs]** and the involvement of Depot Holders [who are responsible persons in the village who will keep a record of persons on treatment and their medications as well as stocks of medicines]. We have observed that patients, who were visited by the CHWs and educated on the need to continue medication, visited the clinic more regularly

Aims and Objectives

The aim of the study is to assess the effectiveness of Community Health Workers in ongoing care and whether their intervention improves treatment adherence and thereby outcome in rural women diagnosed with major depression.

Primary Objectives

1. To assess compliance and adherence to treatment in women with CMD, specifically major depression where adherence will be measured by CHWs using weekly pill counts and regularity of patient visits.
2. To study the outcome of treatment intervention in women with CMD, specifically major depression by scores obtained on the 17-item Hamilton Depression Rating Scale

Secondary Objectives

1. To study outcome of treatment intervention in women with major depression by measuring changes in the quality of life using the WHO Quality of Life [QOL] Scale [29].

Methodology:

Dommasandra, a Primary Health centre area was selected. There are 33 villages coming under the PHC covering a population of 29,117.6 villages were selected based on the distance to the PHC. The survey team consisted of 4 Community Health Workers and a Research Assistant.

A house to house survey was conducted in the villages of the study area of 6 villages by the research investigator to screen for patients with common mental disorders. General Health Questionnaire-28 item version (GHQ) was administered to all adult women (>18years). Those women obtaining a score of ≥5 were invited to participate in the study after obtaining a written informed consent. A demographic profile of the women was obtained using a schedule. The age, marital status, education, family size, type of family, employment

Socio-economic status of the women was obtained using Standard of living Index (SLI). Women who obtained a score of ≥5 on GHQ-28 item version were

interviewed on the Mini International Neuropsychiatric Interview (MINI), a structured interview schedule to confirm a psychiatric diagnosis of major depression The severity of depression was assessed using Hamilton Depression Scale (17 item version, HAMD). HAMD is available in local language and has been used in previous studies in India WHO-QOL (Brev) was used to assess the quality of life of the women with depression. The villages covered by the PHC were randomized into two groups. In the experimental group, patients were monitored regularly by the Community health workers (CHW). Each village had a depot holder who maintained a record of all patients in the village and details of the medication taken. The women with depression who were referred to the PHC were registered. They were given an identity card containing their name, survey number, village and a specific Registration number. The antidepressants selected included either amitryptiline or fluoxetine and the choice was made on the basis of symptom cluster of depression. The outcome was measured at the end of 6 months after the initial interview or treatment completion in both the groups. This included re-administration of Hamilton Depression Rating Scale and the WHO Quality of Life scale.

Results

A total of 814 houses were surveyed out of which 43.61% belong to the treatment as usual group and 56.39% were in the Intervention group. A total of 1055 women between the age group of 18 to 65 were interviewed of whom 873 (82.75%) consented for the study. After obtaining the data on socio-demographic profile, GHQ-28 was administered. GHQ was found to be positive (≥5) in 294(33.68%) of the women. Out of the 294 screened positive 20(6.8%) of the women did not give consent for further assessment. Thereby 274 of the

GHQ+ ve women were administered MINI, a structured psychiatric interview schedule to confirm a diagnosis of major depression as per DSM-IV TR criteria and formed the final sample for the study.The socio-demographic data of the treatment as usual and the intervention group was compared. Overall there were no significant differences in any of the socio-demographic features between the

experimental and the control groups.17.3% women completed 6 months of treatment as compared to 0.8% of women in the treatment as usual group. A higher proportion of women in the treatment as usual group did not come to the treatment centre for consultation with the primary care physician.

There was a statistically significant difference in the number of women registered with a greater proportion from the experimental group.

It was observed that the treatment seeking behaviour was more among the intervention group (54.9%) than among the treatment as usual group (39.3%).

There was a significant improvement in the mean HAMD scores at 6 months in both the treatment as usual and the experimental group. However, there were no between group differences. There was a statistically significant improvement in the mean scores of the physical domain and the psychological domain of quality of life indices in both the groups. However there was no significant difference in the any of QOL domains between the treatment as usual and the intervention groups.

INTRODUCTION

Common mental disorders refer to depression and anxiety syndromes and are among the most important cause of psychiatric morbidity in a primary health[1-3.] The prevalence of Common Mental Disorders [CMD] in primary care settings in India and other Southeast Asian countries ranges between 20 and 45% [4,5] . CMD can result in considerable disability [6] and chronic morbidity [7-10.] CMD has been strongly associated with female gender [11,] poverty [12] and low educational status [13]. Most patients with CMD presenting to the primary care receive inappropriate symptomatic treatment [14.]

Studies from industrialized countries have shown the effectiveness of both drug and psychological intervention in depression in primary care settings[15-17.] However, there are very few published studies on the treatment outcome of CMD from low-income countries[18-21] . The majority of patients with CMD in India and other developing countries receive pharmacotherapy, the clinical effectiveness of which is in the main limited by two factors; patient adherence to the recommended protocol and under-diagnosis and/or sub optimal treatment by primary care doctors[22].

Treatment adherence has been assessed in different studies using various methodologies. Peveler et al [23] assessed prevalence of adherence in the UK using an Electronic Monitoring System and reported that about 40% had discontinued antidepressant medication within 12 weeks of starting treatment. Lin et al. [24] assessed a large sample of patients attending primary care clinics found that 32-42% of patients had discontinued antidepressant medication 6-8 weeks after starting treatment. A study conducted in Goa, India, that compared migraine and fluoxetine in the treatment of CMD found that compliance to treatment among patients with CMD was poor and that majority of them had discontinued their medication due to side effects[20] .The same group of investigators did a randomised placebo controlled trial in patients with CMD attending general

outpatient clinics in two district hospitals in Goa and found that psychiatric outcome was significantly better with antidepressant treatment than with placebo only over a short term period (2 months) but not over a long term period (12 months). They reported adherence rates to antidepressant medication of 46% at 2 months and 26% at 6 months. Common reasons for non-adherence at 2months were side effects, forgetting to take medication and feeling better. At 6 months, the main reasons were feeling better, being physically sick or taking other medication [19]. Srinivasan et al[21] examined the outcome in major depression in individuals resident in a rural community following naturalistic treatment with antidepressants. They reported that many patients did not seek treatment even when treatment was made available in a nearby primary health centre and those who sought treatment discontinued treatment prematurely. Others too have observed that a low proportion of patients diagnosed with CMD had contacted treatment services[25] . Thus, poor adherence to treatment protocol is common among patients diagnosed with CMD in primary care settings and in addition, many patients with CMD do not seek help even when medical treatment is locally available.

There have been many efforts to improve treatment adherence in patients diagnosed with depression at primary care clinics. Studies carried out in the west implementing multilevel interventions and collaborative care has shown to significantly improve treatment adherence [26] and treatment benefit [27]. There are few studies from resource poor countries on improving treatment adherence in primary care patients. A randomized controlled study from Chile using a stepped care approach, reported that 70% of adult female primary care patients in the experimental group had recovered compared with 30% of the usual care group[18.] However, to the best of our knowledge, there is no known literature, which addresses issues related to improving treatment adherence to antidepressant medications in patients diagnosed with depression seeking help from primary care centre in India.

Our project aims at studying whether patient adherence to treatment will improve with the intervention of **Community Health Workers [CHWs]** and the involvement of Depot Holders [who are responsible persons in the village who will keep a record of persons on treatment and their medications as well as stocks of medicines]. We have observed that patients, who were visited by the CHWs and educated on the need to continue medication, visited the clinic more regularly. During their visit, CHWs will also involve family members in the treatment plan. Recruitment of family and friends to support the therapeutic plan and its implementation has also shown to improve treatment compliance [28]. In addition, by involving Community Health Workers and Depot Holders, we are taking treatment of CMD to patients' homes and thereby cutting down their visits to the hospital, which may prove to be both, patient- friendly and cost effective in the long run.

AIM / OBJECTIVES

The aim of the study is to assess the effectiveness of Community Health Workers in ongoing care and whether their intervention improves treatment adherence and thereby outcome in rural women diagnosed with major depression.

Primary Objectives

1. To assess compliance and adherence to treatment in women with CMD, specifically major depression where adherence will be measured by CHWs using weekly pill counts and regularity of patient visits.
2. To study the outcome of treatment intervention in women with CMD, specifically major depression by scores obtained on the 17-item Hamilton Depression Rating Scale

Secondary Objectives

1. To study outcome of treatment intervention in women with major depression by measuring changes in the quality of life using the WHO Quality of Life [QOL] Scale [29].

METHODOLOGY

It is a randomised trial to assess the treatment adherence of women with depression with enhanced community care as intervention.

The methodology will be described under the following headings:

I Study Area:

Dommasandra, a Primary Health centre area was selected. There are 33 villages coming under the PHC covering a population of 29,117. There are 5 sub-centres each with population of 4406, 9153, 4915, 5280 and 5363. 6 villages were selected based on the distance to the PHC. The 6 villages were B.Hosahalli (Population 1017), Gopasandra (Population 613) , Alibommasandra(Population 289), Kadagrahara (Population 393) , Samanhalli (Population 529) and Muthanalur (Population 1846).

II. Subjects :

A house to house survey was conducted in the villages of the study area by the research investigator to screen for patients with common mental disorders. General Health Questionnaire-28 item version (GHQ) was administered to all adult women (>18years). GHQ has been used in previous community studies in India and a standardized translated version in vernacular language is available. Those women obtaining a score of ≥5 were invited to participate in the study after obtaining a written informed consent. In the case of illiterate patients the consent form was read out to the participant and the consenting procedure was witnessed by a neutral observer (Social worker). In addition, treatment history for the last 6 months was ascertained from all the participants. Only treatment naive subjects

were included in the study.Consenting subjects were assessed on the following measures :

III. Methods

1: A demographic profile of the women was obtained using a schedule. The age, marital status, education, family size, type of family, employment, and occupational history were obtained. Any past or family history of mental illness was also asked for.

2: Socio-economic status of the women was obtained using Standard of living Index (SLI). This index was used in the National Family Health Survey 1998-1999 to compare the standards of living between rural and urban areas in India[30] . The SLI is comprised of items such as the type of dwelling, whether residents have access to drinking water, ownership of property, land and livestock, and possession of durable goods like vehicles, television, tractor etc. The scores are tabulated and residents are classified into three categories: Low SLI (0-14), Medium SLI (15-24) and high SLI (25-67). We chose SLI to measure socio-economic conditions as this scale has been well standardized for use in rural India.

3: Women who obtained a score of ≥5 on GHQ-28 item version were interviewed on the Mini International Neuropsychiatric Interview (MINI), a structured interview schedule to confirm a psychiatric diagnosis of major depression according to DSM-IV TR criteria. Any axis I co-morbid diagnosis was also noted.

4: The severity of depression was assessed using Hamilton Depression Scale (17 item version, HAMD). HAMD is available in local language and has been used in previous studies in India [25] .Scores obtained on the HAMD were used as the primary outcome variable. HAMD was administered at baseline and at 6 months

5: WHO-QOL (Brev) was used to assess the quality of life of the women with depression. This questionnaire is available in local language and has been used in a previous study of CMD in rural populations in India[25] . WHO QOL scale consists of 26 items and has 4 domains that measures physical, psychological,

social and environmental component of quality of life. WHO-QOL was administered at baseline and at 6 months.

IV Selection and training of personnel

The survey team consisted of 4 Community Health Workers and a Research Assistant. The health workers were appointed on the basis of the selection criteria that they were all women, from the local community, had studied upto 10th standard and had a previous experience of working in Community Mental Health programmes. The Research Assistant had a Master Degree in Social work in the field of Medicine and Psychiatry. She also had prior experience as a Counsellor in a Family Counselling Centre.

The Community Health workers and the Research Assistant were given a basic training for 3 days in the identification and recognition of common mental disorders. They also underwent sessions to familiarise themselves with the research protocol.

The Research Assistant also under went intensive training for 1 month in administration of MINI, WHO-QOL and Hamilton Depression Scale under the supervision of the principal investigator (KS). The training was in the form of didactic lectures, and practical administration of the tools on the patient attending the Psychiatry OPD in St.John's Medical College hospital.

V Data Collection:

A house-to-house survey was done in the 6 villages by the team of health workers and research investigator. All the women who were in the age of 18 to 65 years were interviewed after obtaining informed consent. A total of 873 women consented for the study and were interviewed.

After obtaining the initial socio-demographic details by the CHWs, the women were administered GHQ-28. If the women scored ≥5, and diagnosed to have major depression on MINI were referred to the weekly clinic in Dommasandra PHC.

VI Treatment randomization (Figure 1).

The villages covered by the PHC were randomized into two groups. In the experimental group, patients were monitored regularly by the Community health workers (CHW). Each village had a depot holder who maintained a record of all patients in the village and details of the medication taken. Patients need to visit the primary health center once a month to consult the physician. The CHWs will visit patients immediately following medical consultation and discuss with the patient and caregivers concerning the need for compliance with treatment. This will be followed by another visit in the subsequent week to enquire about any possible side effects and clarification of any doubts concerning treatment. In addition, CHW'S will call on those patients who have discontinued medication to encourage them to resume treatment. Such pattern of visits will be followed after every monthly consultation with the physician. CHWs will also try and identify reasons for drop out from patients who do not seek help from the physician or have discontinued treatment. In the treatment as usual group, patients diagnosed with depression will be encouraged to seek help from the physician at PHC with no additional input from the CHW. A drop out in this study was defined as any patient who missed at least 2 consecutive appointments with the primary care physician.

VI Referral and Treatment:

The women with depression who were referred to the PHC were registered. They were given an identity card containing their name, survey number, village and a specific Registration number. A separate case sheet was maintained for each of the women. They were then evaluated in detail regarding age, education, past history of mental illness, history of tobacco consumption and any medical conditions. A detailed general physical examination was done followed by systemic examination to rule out any medical ailments. Antidepressant medication was prescribed by a primary health care physician who had had prior training in the recognition and treatment of depression. The antidepressants selected included either amitryptiline or fluoxetine and the choice was made on the basis of symptom cluster of depression.

VII Follow-up

The outcome was measured at the end of 6 months after the initial interview or treatment completion in both the groups. This included re-administration of Hamilton Depression Rating Scale and the WHO Quality of Life scale.

VIII Analysis:

The data was entered on SPSS version 10. The WHO QOL was analyzed separately using an SPSS syntax file that automatically checks, recodes the data and computes the domain scores. Discontinuous data was analyzed using Chi-square and for continuous data Independent sample T-tests were used..

Figure 1. Randomization Process:

<table>
<tr><td rowspan="7"></td><td colspan="4">Villages of Dommasandra PHC are randomised into two groups
Treatment As Usual & Intervention group</td></tr>
<tr><td colspan="4">House to House survey by CHWS using GHQ-28</td></tr>
<tr><td colspan="4">Those +ive by GHQ-28- Administration of MINI by RI. Those +ive by MINI – Referred to</td></tr>
<tr><td colspan="4">Primary Health Centre where Ham-D and WHO QOL scales will be administered by PCP</td></tr>
<tr><td colspan="4">At PHC, patients are given medication and are educated by Primary Care Physician.
Asked to return to PHC after one week</td></tr>
<tr><td colspan="2">Group I - Treatment As Usual</td><td colspan="2">Group II - Intervention by CHWs</td></tr>
<tr><td colspan="2"></td><td colspan="2">CHWs visit patient at home 3-4 days later and imparts Education to patient and family</td></tr>
<tr><td>End of week 1</td><td>Patient returns to PHC. Receives drugs for 2</td><td>At any time during the treatment regimen, if</td><td>End of week 1</td><td>Patient returns to PHC and receives drugs for 2 weeks. Asked to collect balance from DH, 2 weeks later and return to PHC after 1 month</td></tr>
</table>

<table>
<tr><td></td><td>weeks. Asked to collect balance from DH 2 weeks later and return to PHC after 1 month</td><td rowspan="4">the patient ceases to follow instructions, the Depot Holder [DH] visits the patient and documents the reason. There will be no more intervention after that.

A **drop out** in this study is defined as any patient who misses at least 2 consecutive appointments with either the doctor or the Depot Holder.</td><td>End of week 2</td><td>CHWs visit patient at home – encourages patient to continue medication. Enquires about problems faced</td></tr>
<tr><td rowspan="2">End of week 3</td><td rowspan="2">Patient collects drugs from Depot Holder</td><td>End of week 3</td><td>Patient collects drugs from Depot Holder. If not, DH visits patient</td></tr>
<tr><td>End of week 4</td><td>CHWs visit patient at home – Enquires about patient’s health</td></tr>
<tr><td>End of week 5</td><td>Patient returns to PHC and is prescribed medication for 2 months but receives drugs only for 2 weeks.</td><td>End of week 5</td><td>Patient returns to PHC and is prescribed medication for 2 months but receives drugs only for 2 weeks.</td></tr>
</table>

<table>
<tr><td>End of week 7</td><td>Patient collects drugs for 2 weeks from the depot holder.</td><td rowspan="5">If a patient chooses to discontinue treatment before completion of 6 months, due to adverse effects or any other reason, it would be reported as early termination of treatment.</td><td>End of week 7</td><td>Patient collects drugs from Depot Holder. If not, DH visits patient</td></tr>
<tr><td>End of week 9</td><td>Patient collects drugs for 2 weeks from the depot holder.</td><td>End of week 9</td><td>CHWs visit patient at home – Enquires about patient’s health and checks adherence to treatment</td></tr>
<tr><td>End of week 11</td><td>Patient collects drugs for 2 weeks from the depot holder.</td><td>End of week 11</td><td>Patient collects drugs from Depot Holder. If not, DH visits patient</td></tr>
<tr><td rowspan="2">End of week 13</td><td rowspan="2">Patient returns to PHC for follow-up and treatment continues as before until treatment completion</td><td>End of week 13</td><td>Patient returns to PHC for follow-up and treatment continues as before until treatment completion</td></tr>
<tr><td colspan="2">CHWs visit patients only if DH reports that patients have not collected medicines.</td></tr>
<tr><td colspan="5">Hamilton Depression Scale and WHO QOL scale will be administered at the end of 6 months.</td></tr>
</table>

RESULTS

The Results have bee divided into the following sections:

Section 1: Outline of the final status of the study

Section 2: Socio-demographic profile of all the women who consented for the study (N=873)

Section 3: Socio-demographic profile of the study group N=255

Section 4: Analysis of the MINI of the study group

Section 5: Treatment Outcomes and Adherence

Section 6: Comparison between scores of HAM-D and WHO-QOL before and after intervention in the study group

ACTIVITY / RESULTS	TREATMENT AS USUAL GROUP		INTERVENTION GROUP		TOTAL	
Houses surveyed	355		459		814	
Population covered	1604		1928		3532	
	M = 805	F =799	M = 925	F=1003	M = 1730	F =1802
Total number of women aged 18-65 years	465		590		1055	
Number of women who consented for the study	384		489		873	
Number with GHQ >5	138		156		294	
Number with GHQ <5	246		333		579	
MINI not consented	9		11		20	
MINI + [With Depression]	122		133		255	
MINI - [Without Depression]	7		12		19	
Not consented for Post intervention administration of HAM-D, WHO-QOL	11		9		20	

Section 1: Outline of the final status of the study

A total of 814 houses were surveyed out of which 43.61% belong to the treatment as usual group and 56.39% were in the Intervention group. A total of 1055 women between the age group of 18 to 65 were interviewed of whom 873 (82.75%) consented for the study. After obtaining the data on socio-demographic profile, GHQ-28 was administered. GHQ was found to be positive (≥5) in 294(33.68%) of the women. Out of the 294 screened positive 20(6.8%) of the women did not give consent for further assessment. Thereby 274 of the GHQ+ ve women were administered MINI, a structured psychiatric interview schedule to confirm a diagnosis of major depression as per DSM-IV TR criteria and formed the final sample for the study.

Section 2: Socio-demographic profile of all the women who consented for the study (N=873)

		Frequency	Percent
Age	18-25	209	23.9
	26-35	287	32.9
Mean=35.59 yrs	36-45	217	24.9
S.D=11.67 yrs	46-55	105	12.0
	>56	55	6.3
Marital Status	Single	40	4.6
	Married	756	86.6
	Separated/Divorced/ Widow	77	8.8
Educational Status	Illiterate	327	37.5

	Literate	135	15.5
	< 5th standard	130	14.9
	SSLC	210	24.1
	PUC	48	5.5
	Graduate	22	2.5
	Post graduate	1	.1
Employment status	Unemployed	833	95.4
	Employed	40	4.6
Type of Family	Nuclear	526	60.3
	Joint	347	39.7
Family Size	<=4	423	48.5
	>4	450	51.5
History of mental Illness	Present	192	22.0
	Absent	681	78.0
Family History of Mental Illness	Present	91	10.4
	Absent	782	89.6
Socio-economic Status	Low	106	12.1
	Middle	272	31.2
	High	494	56.6
	Uncooperative	1	.1

Among all the women (873) who consented to participate in the study, majority were married. and educated but most of them were unemployed (95.4%). The majority of the women came from nuclear families with average family size being 5.07. There was a past history of mental illness among 22% and a small number of them also had family history of mental illness (10%)

Section 3: Socio-demographic profile of the study group N=255

Variables		Treatment As Usual (Mean Age=38.4)	Intervention (Mean Age=38.4)	
Age	18-25yrs	15(12.3%)	20(15%)	
	26-35 yrs	41(33.6%)	42(31.6%)	
	36-45 yrs	37(30.3%)	39(29.3%)	
	46-55 yrs	22(18%)	23(17.3%)	
	>55 yrs	7(5.7%)	9(6.8%)	
Marital Status	Single	3(2.5%)	5 (3.8%)	
	Married	108(88.5%)	114(85.7%)	
	Separated / Divorced / Widow	11(9%)	14(10.5%)	
Educational Status	Illiterate	71(58.2%)	75(56.4%)	
	Literate	16(13.1%)	18(13.5%)	
	< 5th standard	18(14.7%)	23(17.3%)	
	SSLC	14(11.4%)	14(10.5%)	
	PUC	0	2(1.5%)	
	Graduate	3(2.5%)	1(0.8%)	
Employment Status	Unemployed	113(92.6%)	128(96.2%)	
	Employed	9(7.4%)	5(3.8%)	
Family Size	=<4	53(43.4%)	77(57.9%)	
	>=5	69(56.6%)	56(42.1%)	
Family Type	Nuclear	69(56.6%)	86(64.7%)	
	Joint	53(43.4%)	47(35.3%)	
History of Mental Illness	Present	60(49.2%)	66(49.6%)	

	Absent	62(50.8%)	67(50.4%)
Family History of Mental Illness	Present	22(18%)	30(22.6%)
	Absent	100(82%)	103(77.4%)
Distance to the PHC	<=7kms	73(59.8%)	55(41.4%)
	8-10kms	30(24.6%)	5(3.8%)
	>=11kms	19(15.6%)	73(54.9%)
Socio-economic Status	Low	26(21.3%)	32(24.1%)
	Middle	52(42.6%)	53(39.8%)
	High	44(36.1%)	48(36.1%)

The socio-demographic data of the treatment as usual and the intervention group was compared. Overall there were no significant differences in any of the socio-demographic features between the experimental and the control groups.

Section 4: Analysis of the MINI in the study group

		Treatment As Usual	Intervention	
Major Depressive Episode Current	Present	122(100%)	133(100%)	
Major Depressive Episode – Recurrent	Present	64(52.4%)	85(63.9%)	
	Absent	58(47.5%)	48(36.1%)	
Major Depressive Episode with Melancholic Features Current	Present	120(98.4%)	130(97.4%)	
	Absent	2(1.6%)	3(2.2%)	
Suicide Risk -Current	No Risk	28(22.9%)	40(30.1%)	

	Low Risk	19(15.6%)	38(28.6%)
	Moderate Risk	53(43.4%)	38(28.6%)
	High Risk	22(18%)	17(12.8%)
Panic Disorder	Present	91(74.6%)	76(57.1%)
	Absent	31(25.4%)	57(42.8%)
Panic Disorder without Agarophobia –Current	Present	52(42.6%)	55(41.4%)
	Absent	70(57.4%)	78(58.6%)
Panic Disorder with Agarophobia –Current	Present	52(42.6%)	55(41.4%)
	Absent	70(57.4%)	78(58.6%)
Agarophobia -Current Without history of Panic Disorder	Present	7(5.7%)	9(6.7%)
	Absent	115(94.3%)	124(93.2%)
Social Phobia - Current	Present	60(49.2%)	62(46.6%)
	Absent	62(50.8%)	71(53.4%)
Generalized Anxiety Disorder- Current	Present	106(86.9%)	108(81.2%)
	Absent	16(13.1%)	25(18.8%)

There were no significant differences in any of the clinical features on MINI between the experimental and the control groups including co-moprbid axis I diagnosis.

Section 5: Treatment Outcomes and Adherence

Table 1: Treatment Adherence

	Treatment As Usual	Intervention	Total	
Completed Treatment	1(0.8%)	23(17.3%)	24(9.4%)	
Not completed Treatment	121(99.2%)	110(82.7%)	231(90.6%)	
	122	133	255	

Chi square= 20.25, p<0.001 Very Significant.

17.3% women completed 6 months of treatment as compared to 0.8% of women in the treatment as usual group. The table also shows that the treatment adherence is significantly better in the intervention group than in the treatment as usual group. However, majority in both the groups did not complete treatment as defined by adherence to treatment for 6 months.

Table 2: Pattern of Treatment Adherence

	Treatment As Usual	Intervention	Total	
Completed Treatment	1(0.8%)	20(15%)	21	
Defaulted	34(27.9%)	40(30.1%)	74	
Treatment after Default	0	3(2.3%)	3	
Not come for treatment	87(71.31%)	70(62.6%)	157	
	122	133	255	

A higher proportion of women in the treatment as usual group did not come to the treatment center for consultation with the primary care physician.

Table 3. Women registered in the Primary Health Centre

	Treatment As Usual	Intervention	Total	
Registered	35 (28.7%)	63(47.4%)	98	
Not registered	87(71.3%)	70(52.6%)	157	
	122	133	255	

Chi square value=9.38 p< 0.01

Out of 255 women diagnosed with major depression, 98 (38.4%) registered with the primary health center for treatment. There was a statistically significant difference in the number of women registered with a greater proportion from the experimental group.

Table 4: Treatment seeking for depression of the study group after initial visit by Health workers

	Treatment As Usual	Intervention	Total	
Not gone to any health care facility	52(42.6%)	50(37.6%)	102	
Has visited any health care facility	48(39.3%)	73(54.9%)	121	
Don't know	22(18%)	10(7.5%)	32	
	122	133	255	

It was observed that the treatment seeking behaviour was more among the intervention group (54.9%) than among the treatment as usual group (39.3%). This difference however was not found to be statistically significant.

Section 6: Comparison between scores of HAM-D and WHO-QOL before and after intervention in the study group

Table 1: HAM-D Scores Pre and Post Intervention (Pre N=255, Post N=235)

Scales		Treatment AsUsual-Mean Scores	Intervention Group- Mean Scores	
HAM-D	Pre	18.98±4.77	18.81±4.91	
	Post	11.52±7.32	12.24±5.74	

As has been observed in Table 1 there has been a definite decrease in the severity of the Depression according to mean Hamilton Depression Scores. There was a significant improvement in the mean HAMD scores at 6 months in both the treatment as usual and the experimental group. However, there were no between group differences.

Table 2: WHO-QOL- Mean Scores with Standard Deviation (Pre N=255, Post N=235)

Scales		Treatment As Usual-Scores	Intervention Group-Scores	
Physical Domain	Pre	10.89±2.71	10.96±2.47	
	Post	12.13± 2.71	12.35±2.28	
Psychological Domain	Pre	10.33±2.49	10.42±2.96	
	Post	11.12±2.87	11.46±2.94	
Environmental Domain	Pre	11.00±2.26	11.07±2.36	

	Post	10.92± 2.61	11.21±2.29
Social Domain	Pre	10.96±3.38	11.06±3.78
	Post	11.89±3.36	11.27±3.52

There was a statistically significant improvement in the mean scores of the physical domain and the psychological domain of quality of life indices in both the groups. However there was no significant difference in the any of QOL domains between the treatment as usual and the intervention groups.

Discussion

The present study is a randomized controlled trial to improve treatment adherence to antidepressant medication in rural women diagnosed with major depression who were treatment naïve.

Treatment adherence to the recommended protocol has been identified as one of the major factors in the effective treatment of depression[22]. Various studies have shown that in resource poor countries a large number of individuals diagnosed with CMD do not access help from formal health sector even when they are encouraged to do so [19,21,25]. Local factors such as lack of transportation, financial difficulties, and inability to take time off from daily work have been reported to act as significant barriers to accessing health services[21]. While higher rates of depression are noted among women across the world, the gender differences are more marked in population from low-income countries[13]. Social and economic issues such as poverty, which have been hypothesized to explain the link between female gender and the occurrence of CMD[12], may also influence help seeking behaviour among rural women. Social problems embedded as they are within a family system (interpersonal problem, financial difficulties) may itself act as a significant barrier in seeking professional help[21]. While there have been various attempts to increase treatment retention using collaborative or stepped up care approach in industrialized countries[16], few studies have examined the application of such approaches in resource poor countries[18]. The present study is an attempt to improve help seeking behaviour and treatment adherence and retention in rural disadvantaged women diagnosed with major depression.

Findings from the present study indicate that a significantly greater proportion of women from the experimental group registered for treatment at a rural primary health centre compared to the treatment as usual group. In addition, a significantly larger number of women from the experimental group adhered to the treatment protocol compared to the control group. Thus, enhanced community support using trained volunteers from the community was effective in recruiting women diagnosed with depression into a treatment programme at a primary health centre and helped in better retention of the women in treatment at 6 months. However, it is disturbing to note that in both the treatment as usual as well as in the experimental group, a significantly large number of women did not seek any help from the primary health centre. As private practitioners and private hospitals are generally perceived as more caring compared to Government supported primary health centres, we examined the frequency of help seeking behaviour from other sources between the experimental and the control group. Following the initial interviews by the research team, a greater number of women from the experimental group sought help from local hospitals and private practitioners. These findings suggest that enhanced community support did increase help seeking behaviour among previously untreated rural women diagnosed with major depression. Thus, the primary objective of the study that enhanced community support would result in better treatment compliance was borne out by the findings of the present study.

The second objective of the present study was to examine outcome of depression at 6 months. HAMD scores and WHO-QOL were the main objective measures to study outcome. We did not find any statistically significant differences in both HAMD and WHO-QOL scores at 6 months between the experimental and the control groups. This is contrast to studies that report improved treatment adherence and better outcomes in

depression[16,18] . However, two prospective studies that assessed outcome in depressed patients treated naturalistically observed that treatment with antidepressants did not significantly influence outcome[32,33] . Clinical effectiveness of antidepressant medication in mild depression seen commonly among primary care attendees is yet to be established[34], while severity of depression and ongoing social difficulties are important determinants of consultation rate in patients with depression in primary care[35] . This has prompted a large randomized clinical trial to examine the effectiveness of antidepressant medication in patients presenting with depression in primary care[36] . In the present study, majority of patients had mild depression at baseline with a mean HAMD score of 18, which may explain lack of differences in outcome among patients who adhered to treatment recommendations compared to defaulters. In addition, it has also been suggested that the mere act of interviewing and advising them to access help itself may be therapeutic for some individuals with CMD[25] . It is also possible that some of the clients might have sought help from other sources. Our data indicate that both among the experimental group and the control group had visited other health care facilities. Thus, our intervention might have also helped to increase awareness concerning CMD among subjects prompting consultation with formal health sector. Unfortunately, we could not obtain details concerning these medical encounters.

To conclude, enhanced community support to rural disadvantaged women with major depression resulted in greater women seeking help and retaining them in treatment. However, a significant number of women with major depression still opted not to seek help at all or defaulted from treatment recommendations. More importantly, there were no significant differences in outcome as measured by changes in HAMD and WHO-QOL between the group that received enhanced community support and those that received treatment as usual. Future studies are needed to determine the threshold level of depression that requires medical intervention and those that can be managed through psychosocial intervention. In resource poor countries it is also important to examine whether psychosocial interventions can be provided by trained community level workers who have far easier access to community. The finding that a high proportion of subjects with CMD did not access locally available health services has important public health implications. It has been suggested that providing mental health training to general medical and traditional practitioners might help in the early detection of CMD and to institute appropriate treatment. As large numbers do not access formal help from the health sector, merely making psychiatric services available at primary health centre may not address the unmet needs of the population. While emphasis in various public health programmes has been on enhancing skills of primary care practitioners in early identification and instituting appropriate treatment for CMD, increasing awareness concerning CMD among population is pivotal to improving access to treatment from formal health sector. Finally, and importantly this programme helped in enhancing the skills of CHWs in the domain of diagnosis, early identification and counselling of patients with CMD. Increasingly, given the relative lack of mental health professionals in rural areas, paraprofessionals are expected to shoulder the burden of meeting the unmet needs of large numbers of clients with CMD. Randomized controlled trials with trained paraprofessionals have shown that they are as effective as mental health professionals in the identification and management of mild depression[37]. In future studies, we intend to examine the compare the effectiveness of intervention using the services of our trained CHW's to that of primary care physician.

REFERENCES

1. Goldberg D, Lecruiber Y. Form and frequency of mental disorders across cultures. In: Ustun TB & Sartorius, N. (Eds), Mental illness in general health care: an International study, 1995, pp.323-334, Chichester: John Wiley & Sons.
2. Harding TW, De Arango MV, Baltazar J et al. Mental disorders in primary health Care: a study of their frequency and diagnosis in four developing countries. Psychological Medicine (1980);10: 231-241.
3. Sen B, Williams P. The extent and nature of depressive phenomena in primary health care: A study in Calcutta, India. British Journal of Psychiatry (1987); 151: 486-493.
4. Shamasundar C, Krishnamurthy S, Prakash O, Prabhakar N, Subhakrishna D. Psychiatric morbidity in a general practice in an Indian City. BMJ (1986); 292: 1713-5
5. Vikram Patel; The Epidemiology of common mental disorders in South Asia. NIMHANS Journal, (1999): 17 (4); 307-327
6. Ormel J, Vonkorff M, T. Bedirhan Ustun, Stephano Pini, Ailsa Korten, Oldehinkel T. Common Mental Disorders and Disability across cultures. Results from the WHO Collaborative study on Psychological problems in General Health Care. JAMA. (1994); 272; 22, 1741-1748.
7. Goldberg D, Blackwell B. Psychiatric illness in general practice: A detailed study using a new method of case identification. BMJ. (1970); 2: 439-443.
8. Mann AH, Jenkins R, Belsey E. The 12 month outcome of patients with neurotic illness in general practice. Psychological Medicine. 1981; 2: 535-550.
9. Patel V, Todd CH, Winston M et al. The outcome of common mental disorders in Harare, Zimbabwe. British Journal of Psychiatry. 1998; 172: 53-57.
10. Weich S, Churchill R, Lewis G et al. Do socio-economic risk factors predict the incidence and maintenance of psychiatric disorders in primary care ? Psychological Medicine. 1997; 27: 73-80.
11. Kishore J, Reddaiah V, Kapoor V et al. Characteristics of mental morbidity in a rural primary health center of Haryana. Indian Journal of Psychiatry. 1996; 38: 137-142.
12. Patel V, Periera J, Coutinho L et al. Poverty, psychological disorder and disability in primary care attenders in Goa, India. British Journal of Psychiatry. 1988; 171: 533-536.
13. Mumford DB, Saeed K, Ahmad I et al. Stress and psychiatric disorder in rural Punjab. A community survey. British Journal of Psychiatry. 1997; 170: 473-478.
14. Srinivasan K, Srinivasamurthy R. Multiple somatic complaints in primary health care settings in tropical countries. Tropical Doctor.1986; 16: 18-21.
15. De Almeida Fleck MP, Simon G, Herrman H et al. Longitudinal investigation of depression outcomes group. Major depression and its correlates in primary care settings in six countries : 9-month follow-up study. British Journal of Psychiatry. 2005; 186: 41-47.

16. Katon W, Russo J, Von Korff M et al. Long term effects of a collaborative care intervention in persistently depressed primary care patients. Journal of Internal Medicine. 2002; 17: 741-748.
17. Simon GE, Chisholm D, Treglia M et al. LIDO group. Course of depression, health service costs, and work productivity in an International primary care study. General Hospital Psychiatry. 2002; 24: 328-335.
18. Araya R, Rojas G, Fritsch R et al. Treating depression in primary care in low income women in Santiago, Chile: a randomized controlled trial. Lancet. 2003; 361: 995-1000.
19. Patel V, Chisholm D, Rabbe-Hesketh S et al. Efficacy and cost-effectiveness of drug and psychological treatments for common mental disorders in general health care in Goa, India: A randomized, controlled trial. Lancet. 2003; 361:33-39.
20. Periera J, Patel V. Which anti depressants are best tolerated in primary care? A pilot randomized trial in Goa. Indian Journal of Psychiatry. 1999; 41: 358-363.
21. Srinivasan K, Isaacs A, Thomas T, Jayaram G. Outcomes of common mental disorders in a rural community in South India. Indian Journal of Social Psychiatry. 2006; 22: 110-115.
22. WHO; Adherence to long-term therapies. Evidence for action; WHO (2003); pp 65
23. Peveler R, Charles George, Ann-Louise Kinmonth, Michael Campbell, Chris Thomsonl. Effect of antidepressant drug counselling and information leaflets on adherence to drug treatment in primary care: randomised controlled trial. British Medical Journal, 1999, 319:612-615
24. Lin EH et al. Low-intensity treatment of depression in primary care: Is it problematic? General Hospital Psychiatry, 2000, 22: 78-83.
25. Chisholm D, Sekar K, Kumar K et al. Integration of mental health care into primary care : demonstration of cost-outcome study in India and Pakistan. British Journal of Psychiatry. 2000; 176: 581-588.
26. Wayne Kayton, Michael Vonkorff, et al. Stepped Collaborative Care for Primary Care patients with persistent symptoms of Depression Arch Gen Psychiatry. (1999); 56; 1109-1115
27. Vergouwen A, Bakker A, Katon W J, et al. Improving adherence to antidepressants: J Clin Psychiatry (2003) 64:12; 1415-1420
28. World Health Organization. World Health Report (2001). World Health Organization Geneva, Switzerland pp. 60
29. WHO Quality of Life Scale (Abbreviated version) (1998). Psychological Medicine; 28: 551-558.
30. Patel V. Pereira J and Mann A.H.. Somatic and Psychological models of common mental disorder in primary care in India. Psychological Medicine, (1998); 28, 135-143
31. Sheehan DV, Lecubrier Y, Harnett-Sheehan K, Amorim P, Janavs J, Weiller E, Hergueta T, Baker R, Dunbar G: he Mini International Neuropsychiatric Interview (MINI): The development and validation of a structured Diagnostic Psychiatric Interview; Journal of Clinical Psychiatry 1998; 59 (Suppl 20): 22-33
32. Brugha TS, Bebbington P, MacCarthy B et al. Antidepressants may not assist recovery in practice: a naturalistic prospective study. Acta Psychiatrica Scandinavica 1992; 86: 5-11.

33. Ronalds C, Creed F, Stone K et al. The outcome of anxiety and depressive disorders in general practice. British Journal of Psychiatry 1997; 171: 427-433.
34. Hermens ML, van Hout AP, Terluin B, Ader HJ, Penninx BW, van Mar wijk HW, Bosmans JE, van Dyck R, de Haan M. Clinical effectiveness of usual care with or without antidepressant medication for primary care patients with minor or mild-major depression: a randomized equivalence trial. BMC Med 2007; 5: 36
35. Ronalds C, Kapur N, Stone K, Webb S, Tomenson B, Creed F. Determinants of consultation rate in patients with anxiety and depressive disorders in primary care. Fam Pract. 2002; 19: 23-28.
36. Chatwin J, Kendrick T, Thread study group. Protocol for the THREAD (Threshold for antidepressant) study: a randomized controlled trial to determine the clinical and cost-eefectiveness of antidepressant plus supportive care, versus supportive care alone for mild to moderate depression in UK general practice. Family Pract 2007; 8:2
37. den Boer PCAM, Wiersma D, Russo S, van den Bosch RJ. Paraprofessionals for anxiety and depressive disorders. Cochrane Database of Systematic Reviews 2005, Issue 2. Art. No: CD004688.DOI:10.1002/14651858.CD004688.pub2.