

SMART Mental Health Statistical Analysis Plan Final Date: 24-11-2017

SMART Mental Health

Innovative provision of primary mental health care in India: The Systematic Medical Appraisal, Referral and Treatment (SMART) Mental Health Programme

Statistical Methodology- SAP and Shells

Author: Anadya Prakash Tripathi, Statistician

Document status: Final

Release date: 24-11-2017

Number of pages: 26

Table of c	ontents:	Page Page
Smart me	ntal health Visit schedule and analysis for visit	4
Data seleo	ction criteria for Analysis	4
Smart me	ntal health Final Statistical Analysis plan	4
Primary A	nalysis	4
Case cont	rol Analysis of Primary objective	5
Secondary	y Analysis	5
Depressio	n and Anxiety Score	5
Demogra	phic and Socioeconomic characteristics	5
Statistical	Analysis of KAB and BACE	5
Stressful e	events	6
Sharing pe	ersonal problems	6
Assessme	nt of Alcohol and substance use	6
Past histo	ry of illness	6
Subject re	ferral by ASHA and PHC doctors	6
Smart m	ental health Mock shells tables	
Table 1:	Demographic and socioeconomic Characteristics	7
Table 2:	Summary for KAB	8
Table 3:	Mean scores and change in Mean scores of KAB Questions	14
Table 4:	Summary for BACE	15
Table 5:	Mean scores and Change in Mean scores for each barrier in	
the BACE		19
Table 6:	Percentage reporting and ranks for each barrier in the BACE	
ASHA scre	en positive	20
Table 7a:	Summary of screening Status and severity of anxiety and	
depressio	n	21
Table 7b:	Summary of Anxiety and Depression Score of ASHA screen	
positive		21
Table 7c:	Summary of Patients who are Screened Positive by ASHA	22
Table 8a:	Change in Depression/Anxiety Score from Baseline to Post	
Interventi	on in screen positive	23
Table 8b:	Change in Depression/Anxiety Score from Baseline to Post	
Interventi	on for those who had a score >=10 at the beginning of the	
interventi	on as screened by ASHAs	23

Table 9a: Summary of stressful question for the Patients who are	
Screened Positive by ASHA	24
Table 9b: Summary of stressful events among the Patients who have	
Depression or Anxiety Score >=10	24
Table 10: Summary of Stressful Events for the Patients who are	
Screened Positive by ASHA	25
Table 11: Summary of Sharing Personal Problems for the Patients who	
are screened Positive by ASHA	25
Table 12: Summary of Assessment of Alcohol and Substance Use for	
the ASHA screened positive Patients	26
Table 13: Summary of Past History of the ASHA screened positive	
Patients	27
Table 14a: Summary of treatment History among ASHA screened	
positive Patients	28
Table 14b: Summary of treatment History during intervention among	
ASHA screened positive Patients	28
Table 14c: Summary of treatment compliance among treated patients	
of ASHA screened	28
Table 15: Summary of for Utilization of Health Services for Screen	
Positive subjects	29
Table 16a: Case control analysis of Change in Depression/Anxiety Score	
from Baseline to Post Intervention for those who had a score >=10 at	
the beginning of the intervention	30
Table 16b: Case control analysis for health service utilization	31
Table 17: Subject Referrals during ASHA screening	32

Smart mental health Visit schedule and analysis for visit:

The study will be reported in mainly 2 category:-

- 1. Baseline (As applicable, this will includes ASHA screening data available in in ASHA
- Screening 1 and ASHA follow up 1. OR Baseline data collected by study interviewers)
- 2. Post Intervention (collected by study interviewers)

All the subject at post intervention are screen positive subjects. They were screened positive either at Baseline by study interviewers or at Intervention visits (ASHA screening 1 and ASHA follow-up 1) by ASHA. All the screen positive subjects were followed by ASHAs which is available in the ASHA follow up data.

Unless otherwise stated, the summary tables will be presented under 2 category:-

- 1. Baseline
- 2. Post Intervention

The difference between Baseline and Post Intervention will provide effect of intervention.

Apart from the Post Intervention data, post stigma data was also collected. At the time of creating derived data for post Intervention, both data (Post Intervention and post stigma) are appended together and created a single data set. A flag variable containing record ("Post Intervention" & "post stigma") was created was created in derived data set to identify such records.

Unless otherwise stated, all the analysis will be presented for all the subject who are screen positive by ASHA.

Data selection criteria for Analysis:

Unless otherwise stated, for baseline we have to use ASHA screening (ASHA screening 1 and ASHA follow-up 1) data. At post intervention we have to use Post intervention data collected by study interviewers linked with patient ID of ASHA screen positive data.

For certain tables the information at baseline may not be collected by ASHA during their screening. For all such instance, Baseline data collected by study interviewers will be used linked with patient ID of ASHA screen positive data.

Smart mental health Final Statistical Analysis plan Primary Analysis:

The primary objective of the study is:-

To see the difference in anxiety and depression score and health service utilization among the mental health screen positive subject post intervention.

The screen positive subjects at baseline will be looked for their past history for mental health service utilization. The subjects who responded "Yes" against question number 56 "Did you get treated for that mental disorder?" are proportion of subject at baseline who used mental health service.

At post intervention, the number of subjects used health service can be taken from Doctors follow-up data.

The count and percentage will be provided for the subjects who are screen positive for utilization of health services. Proportion of mental health service utilization at baseline and post intervention among the screen positive subject will be statistically analyze by McNemar test. The P-value for comparison of will be presented in same table.

A separate table will be provided for subjects screen positive subjects who actually visited doctor for their treatment at time of intervention. The count and percent by visit will be provided for this.

Case control Analysis of Primary objective:

All the subjects screened positive by ASHA are case here. The subjects who mental health are screen negative by ASHA, but screen positive by interviewer are kind of control in this study setup. Such subjects will be called as control.

A case control analysis will be performed to assess the difference in anxiety and depression score and mental health service utilization.

For this difference in anxiety and depression score for individual subjects will be computed from ASHA screen data and post intervention data. Further this difference in case and control will be statistically analyses by 2 independent sample t-test. Difference of difference in score between case and control along with p-value will be presented.

For health service utilization between cases and control, Count along with percent and Chi- square P-value will be presented.

Secondary Analysis Depression and Anxiety Score:

The subjects are classified as screen positive if he/she fulfil either one of below mentioned three category:-

- 1. Depression Sore ≥10
- 2. Anxiety Score ≥10
- 3. Suicidal tendency Score ≥1

The depression and anxiety will be categorized as Normal if their total score is in between 0-

4. The score in between 5-9 will be classify as Mild. The score in between 10-14 will be classify as moderated. The score of 15 or greater will be treated as severe.

The Anxiety and Depression score will be categorized by their severity. The count and percentage for depression and Anxiety at baseline and post baseline will be presented by severity. A separate table will be presented for depression score ≥ 10 and anxiety score ≥ 10 at baseline and post intervention.

A separated table will be provides for the only screen positive subjects with the count and percentage of the symptoms which lead them to be screen positive.

The summary statistics (N, Mean, STD, Min and Max) for anxiety and depression score by visit will be presented. The difference in score between baseline and post intervention will be summarized in similar fashion. The mean difference in score between baseline and post intervention will be statistically analyzed by paired t-test. The p-value from the analysis will be presented in same table.

Demographic and Socioeconomic characteristics:

The count and frequency for the Social characteristic like Gender, occupation, education and marital status will be presented. Age will be summarized by mean SD and range. The occupation and education was not collected at post intervention. Hence the record from baseline will be taken to post intervention for occupation and education.

Statistical Analysis of KAB and BACE:

For every question related to KAB and BACE, the count and percentage will be presented for every response for the concern question.

Further to that for every question, mean score and SD along with number of people responded to different questions of KAB and BACE will be presented. The difference in score between baseline and post intervention will also be analyses by t-test. The mean SD and the number of people responded at both visit along with p-value will be presented.

For KAB the Total Behaviors SCORE (Except First Question) and For BACE, the Total BACE Score, will also be analyzed and summarized in similar fashion.

A separate table for BACE will be presented for % reporting barrier to any degree and % reporting as a major barrier along with their rank for highest proportion rating as a major barrier. The difference in proportion for %reported a major barrier will be analyses by two- proportion z-test and corresponding p-value will pre presented.

Stressful events:

The count and percentage will be provided for the screen positive subjects for the questions of stressful events for which they responded as yes at baseline.

A separate table will provided for the questions of stressful events for which they responded as yes for the subjects who had Depression or Anxiety Score >=10.

The stressful events will be summarized in 4 category (0, 1, 2-3, \geq 4) by count and percentage. Also Descriptive Statistics (n, mean, SD, Min, and Max) for the patients who have total score greater than 1 will be provided.

Sharing personal problems:

The count and percentage will be provided for those subjects who had responded yes for the Question "When you have a personal problem do you share it with anyone?" at baseline.

Assessment of Alcohol and substance use:

The count and percentage will be provided for those subjects who had responded yes for all the 10 different question of alcohol and substance use section.

Past history of illness:

The count and percentage will be provided for those subjects who had responded yes for the questions of heart attack or angina or stroke or diabetes or cancer.

The count and percentage will be provided separately for those subjects who had responded yes for the questions of mental disorder with count and percentage for those subjects who had responded yes for the questions "Did you get treated for that mental disorder?" in similar fashion.

Subject referral by ASHA and PHC doctors:

The count and percentage will be provided for those subjects who were referred by ASHA to PHC doctor during intervention and among all such screen positive subjects again count and percentage will be provided for those subjects who were referred by PHC doctor for more specialized care.

	Baseline	Post Intervention
	(N=XX)	(N=XX)
Characteristics	n%	n%
Gender		
Female	xx(xx.x%)	xx(xx.x%)
Male	xx(xx.x%)	xx(xx.x%)
Occupation		
Housewife/Retired	xx(xx.x%)	xx(xx.x%)
Organized Sector	xx(xx.x%)	xx(xx.x%)
Other	xx(xx.x%)	xx(xx.x%)
Unorganized Sector	xx(xx.x%)	xx(xx.x%)
Education		
Graduate/Postgraduate	xx(xx.x%)	xx(xx.x%)
High School	xx(xx.x%)	xx(xx.x%)
No School	xx(xx.x%)	xx(xx.x%)
Other	xx(xx.x%)	xx(xx.x%)
Primary School	xx(xx.x%)	xx(xx.x%)
Marital Status		
Currently Married	xx(xx.x%)	xx(xx.x%)
Never Married	xx(xx.x%)	xx(xx.x%)
Separated/Divorced/Widowed	xx(xx.x%)	xx(xx.x%)
Age(Years)		
Mean(SD)	xx.xx(xx.xxx)	xx.xx(xx.xxx)
Range	xx.x; xx.x	xx.x; xx.x

Table1: Demographic and Socioeconomic characteristics

N=Total no. of patients in that visit. n= No. of patients with particular characteristic.

Table 2: Summary for KAB

	Question	Baseline	Post Intervention
		(N=XX)	(N=XX)
		n%	n%
Context*	Have you seen or heard any information about mental	health or mental illr	ness issues in the last ye
	in any of these ways?		
	[Newspaper/TV]	xx(xx.x%)	xx(xx.x%)
	[Other]	xx(xx.x%)	xx(xx.x%)
	[People talking about it/ Other]	xx(xx.x%)	xx(xx.x%)
	[People talking about it]	xx(xx.x%)	xx(xx.x%)
	[TV/Health center/People talking about it / Other]	xx(xx.x%)	xx(xx.x%)
	[TV/ Other]	xx(xx.x%)	xx(xx.x%)
	[TV/People talking about it/ Other]	xx(xx.x%)	xx(xx.x%)
	[TV]	xx(xx.x%)	xx(xx.x%)
	Where do people in this community first go to seek car	e for mental illness?	,
	[Hospital]	xx(xx.x%)	xx(xx.x%)
	[Local clinic]	xx(xx.x%)	xx(xx.x%)
	[Neighbor/ Community Member]	xx(xx.x%)	xx(xx.x%)
	[Nowhere/ Care is not available]	xx(xx.x%)	xx(xx.x%)
	[Other]	xx(xx.x%)	xx(xx.x%)
	[Religious or spiritual advisor]	xx(xx.x%)	xx(xx.x%)
	[Traditional healer]	xx(xx.x%)	xx(xx.x%)

	Do any of the following people you know have a	mental illness?	
	[Family member in this household]	xx(xx.x%)	xx(xx.x%)
	[Family member outside this household]	xx(xx.x%)	xx(xx.x%)
	[Friends/Acquaintance]	xx(xx.x%)	xx(xx.x%)
	[Neighbor]	xx(xx.x%)	xx(xx.x%)
	[No one known]	xx(xx.x%)	xx(xx.x%)
	[Someone else]	xx(xx.x%)	xx(xx.x%)
Knowledge	Mentally ill people tend to be violent		
	Agree Slightly	xx(xx.x%)	xx(xx.x%)
	Agree Strongly	xx(xx.x%)	xx(xx.x%)
	Disagree Slightly	xx(xx.x%)	xx(xx.x%)
	Disagree Strongly	xx(xx.x%)	xx(xx.x%)
	Don't know	xx(xx.x%)	xx(xx.x%)
	Neither agree or disagree	xx(xx.x%)	xx(xx.x%)
	People with mental illness can't live a good rewa	rding life	
	Agree Slightly	xx(xx.x%)	xx(xx.x%)
	Agree Strongly	xx(xx.x%)	xx(xx.x%)
	Disagree Slightly	xx(xx.x%)	xx(xx.x%)
	Disagree Strongly	xx(xx.x%)	xx(xx.x%)
	Don't know	xx(xx.x%)	xx(xx.x%)
	Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

People with severe mental problems can fully recover

Agree Slightly	xx(xx.x%)	xx(xx.x%)
Agree Strongly	xx(xx.x%)	xx(xx.x%)
Disagree Slightly	xx(xx.x%)	xx(xx.x%)
Disagree Strongly	xx(xx.x%)	xx(xx.x%)
Don't know	xx(xx.x%)	xx(xx.x%)
Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

Medication can be an effective treatment for people with mental health problems

Agree Slightly	xx(xx.x%)	xx(xx.x%)
Agree Strongly	xx(xx.x%)	xx(xx.x%)
Disagree Slightly	xx(xx.x%)	xx(xx.x%)
Disagree Strongly	xx(xx.x%)	xx(xx.x%)
Don't know	xx(xx.x%)	xx(xx.x%)
Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

Attitude Mentally ill people Agree Slightly Agree Strongly **Disagree Slightly**

Mentally ill people shouldn't get married		
Agree Slightly	xx(xx.x%)	xx(xx.x%)
Agree Strongly	xx(xx.x%)	xx(xx.x%)
Disagree Slightly	xx(xx.x%)	xx(xx.x%)
Disagree Strongly	xx(xx.x%)	xx(xx.x%)
Don't know	xx(xx.x%)	xx(xx.x%)
Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

People with mental health problems are far less of a danger than most people suppose

Agree Slightly	xx(xx.x%)	xx(xx.x%)
Agree Strongly	xx(xx.x%)	xx(xx.x%)
Disagree Slightly	xx(xx.x%)	xx(xx.x%)
Disagree Strongly	xx(xx.x%)	xx(xx.x%)
Don't know	xx(xx.x%)	xx(xx.x%)
Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

We need to adopt a far more tolerant attitude toward people with mental illness in our society

Agree Slightly	xx(xx.x%)	xx(xx.x%)
Agree Strongly	xx(xx.x%)	xx(xx.x%)
Disagree Slightly	xx(xx.x%)	xx(xx.x%)
Disagree Strongly	xx(xx.x%)	xx(xx.x%)
Don't know	xx(xx.x%)	xx(xx.x%)
Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

People with mental health problems shouldn't be given any responsibility

xx(xx.x%)	xx(xx.x%)
xx(xx.x%)	xx(xx.x%)
	xx(xx.x%) xx(xx.x%) xx(xx.x%) xx(xx.x%)

Behavior	I would be willing to live with someone with a mental health problem			
	Agree Slightly	xx(xx.x%)	xx(xx.x%)	
	Agree Strongly	xx(xx.x%)	xx(xx.x%)	
	Disagree Slightly	xx(xx.x%)	xx(xx.x%)	
	Disagree Strongly	xx(xx.x%)	xx(xx.x%)	
	Don't know	xx(xx.x%)	xx(xx.x%)	
	Neither agree or disagree	xx(xx.x%)	xx(xx.x%)	

I would be willing to work with someone	e with a mental health problem
Agree Slightly	xx(xx.x%)

Agree Strongly	xx(xx.x%)	xx(xx.x%)
Disagree Slightly	xx(xx.x%)	xx(xx.x%)
Disagree Strongly	xx(xx.x%)	xx(xx.x%)
Don't know	xx(xx.x%)	xx(xx.x%)
Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

xx(xx.x%)

I would be willing to live nearby someone wi	ith a mental health problem
--	-----------------------------

Agree Slightly	xx(xx.x%)	xx(xx.x%)
Agree Strongly	xx(xx.x%)	xx(xx.x%)
Disagree Slightly	xx(xx.x%)	xx(xx.x%)
Disagree Strongly	xx(xx.x%)	xx(xx.x%)
Don't know	xx(xx.x%)	xx(xx.x%)
Neither agree or disagree	xx(xx.x%)	xx(xx.x%)

I would be willing to continue a relation	nship with a friend who developed a m	ental health problem
[Family]	xx(xx.x%)	xx(xx.x%)
[Friends/ Family]	xx(xx.x%)	xx(xx.x%)
[Friends]	xx(xx.x%)	xx(xx.x%)
[No one]	xx(xx.x%)	xx(xx.x%)

*A subject can be counted more than once for context questions and only top 5 are reported. KAB=Knowledge, Attitude, Behavior.

Table 3: Mean scores and change in Mean scores of KAB Questions:

		Baseline	Post intervention	Post intervention- Baseline
Category	Question	N, Mean(SD)	N, Mean(SD)	N, Mean(SD) P-value
Knowledge	Mentally ill people tend to be violent	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	People with mental illness can't live a good, rewarding life	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	People with severe mental health problems can fully recover	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	Medication can be an effective treatment for people with mental health			
	problems	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Attitude	Mentally ill people shouldn't get married	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	People with mental health problems are far less danger than most people			
	suppose	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	We need to adopt a far more tolerant attitude toward people with mental			
	illness in our society	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	People with mental health problems shouldn't be given any responsibility	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Behavior	I would be willing to live with someone with a mental health problem	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	I would be willing to work with someone with a mental health problem	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	I would be willing to live nearby with someone with a mental health problem	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	I would be willing to continue a relationship with a friend who developed a			
	mental health problem	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
	Overall Behaviors SCORE	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx

*P value is calculated using t-test .KAB=Knowledge, Attitude, Behavior

For mean of difference, subject who have responded at both visit, have been considered for summary.

Table4: Summary of BAC

Question	Baseline	Post intervention
	(N=XX)	(N=XX)
	N(%)	N(%)
Concern that I might have s	seen as weak for having a mental he	ealth problem
A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)
Concern that it might harm	my chances when applying for jobs	5
A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)
Concern about what my fai	mily might think / say / do or feel	
A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Feeling embarrassed or ashamed

A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Concern that I might be seen as crazy

A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Concern that I might be seen as bad parents

A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Concern that people I know might find out

A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Concern that people might not take me seriously if they found out I was having professional care

A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Not wanting a mental health problem to be on my medical records

A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Concern that my children may be taken in to care or that I may lose access or custody without my consent

,		
A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

Concern that what my frien	ds might think/ say or do	
A little	xx(xx.x%)	xx(xx.x%)
A lot	xx(xx.x%)	xx(xx.x%)
NA	xx(xx.x%)	xx(xx.x%)
Not at all	xx(xx.x%)	xx(xx.x%)
Quite a lot	xx(xx.x%)	xx(xx.x%)

at work might think/ say or do	
xx(xx.x%)	xx(xx.x%)
	xx(xx.x%) xx(xx.x%) xx(xx.x%)

Table 5: Mean Scores and Change in mean scores for each barrier in the BACE

Question	Baseline N, Mean(SD)	Post intervention N, Mean(SD)	Post intervention-Baseline N, Mean(SD) P-value
Concern that I might be seen as weak for having a mental health problem	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern that it might harm my chances when applying for jobs	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern about what my family think, say do or feel	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Feeling embarrassed or ashamed	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern that I might be seen as 'crazy'	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern that I might be seen as bad parents	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern that people I know might find out	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern that people might not take me seriously if they found out I was			
having professional care	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Not wanting a mental health problem to be on my medical records	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern that my children may be taken in to care or that I may lose access			
or custody without my consent	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern about what my friends might think, say or do	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Concern about what people at work might think, say or do	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx
Overall BACE score	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx)	xx, xx.xx(xx.xxx) 0.xxxx

*P value is calculated using t-test. BACE=barrier to access care evaluation-Treatment Stigma Subscale. For mean of difference, Subject who have responded to both the visit, have been considered for summary.

Table 6: Percentage reporting and ranks for each barrier in the BACE ASHA screen positive

	Bas	eline		Post Intervention				
	%reporting barrier to	%reporting as major	***	%reporting barrier to	%reporting as major	***	* P-Value	
Question	any degree	barrier (a lot)	Rank	any degree	barrier (a lot)	Rank	Visit 2-3	
Concern that I might be seen as weak for having a mental health problem	xx.xx	xx.xx	x	xx.xx	xx.xx	x	0.xxx	
Concern that it might harm my chances when applying for jobs	xx.xx	xx.xx	x	xx.xx	xx.xx	x	0.xxx	
Concern about what my family might think, say, do or feel	xx.xx	XX.XX	x	xx.xx	xx.xx	x	0.xxx	
Feeling embarrassed or ashamed	xx.xx	xx.xx	x	xx.xx	XX.XX	x	0.xxx	
Concern that I might be seen as crazy	XX.XX	xx.xx	x	xx.xx	XX.XX	x	0.xxx	
Concern that I might be seen as a bad parent	XX.XX	xx.xx	x	xx.xx	XX.XX	x	0.xxx	
Concern that people I know might find out	xx.xx	xx.xx	x	xx.xx	xx.xx	х	0.xxx	
Concern that people might not take me seriously if they found out I was having professional care	xx.xx	xx.xx	x	xx.xx	XX.XX	x	0.xxx	
Not wanting a mental health problem to be on my medical records	xx.xx	xx.xx	x	xx.xx	xx.xx	x	0.xxx	
Concern that my children may be taken into care or that I may lose access or custody without my consent	xx.xx	xx.xx	x	xx.xx	xx.xx	x	0.xxx	
Concern about what my friends might think, say or do	xx.xx	xx.xx	x	xx.xx	xx.xx	х	0.xxx	
Concern about what people at work might think, say or do	xx.xx	XX.XX	х	xx.xx	XX.XX	х	0.xxx	
Overall Mean	XX.XX	XX.XX	х	xx.xx	xx.xx	х	0.xxx	

* P-value calculated based on difference in proportion reported as major barrier.

*** Rank (1=item has highest proportion rating as a major barrier)

Table 7a. Summary of screening Status and severity of anxiety and depression

			Screening Status		Anxiety			Dep		
Screened by	Visit	Ν	Positives	Negatives	Mild	Moderate	Severe	Mild	Moderate	Severe
			n (%)	n (%)	5-9	10-14	>=15	5-9	10-14	>=15
ASHA	Baseline	xxxxx	xxxx (xx.xx)	xxxx (xx.xx)	xxx (xx.xx)					
	Post Intervention	xxxxx	xxxx (xx.xx)	xxxx (xx.xx)	xxx (xx.xx)					
Interviewer	Baseline	xxxxx	xxxx (xx.xx)	xxxx (xx.xx)	xxx (xx.xx)					
	Post Intervention	xxxxx	xxxx (xx.xx)	xxxx (xx.xx)	xxx (xx.xx)					

Table 7b: Summary of Anxiety and Depression Score of ASHA screen positive

Category	Severity	Total Score	Baseline (N=xx) n (%)	Post intervention (N=XX) n (%)
Anxiety	Normal	0-4	xxxx(xx.xx)	xxxx(xx.xx)
-	Mild	5-9	xxxx(xx.xx)	xxxx(xx.xx)
	Moderate	10-14	xxxx(xx.xx)	xxxx(xx.xx)
	Severe	>=15	xxxx(xx.xx)	xxxx(xx.xx)
Depression	Normal	0-4	xxxx(xx.xx)	xxxx(xx.xx)
·	Mild	5-9	xxxx(xx.xx)	xxxx(xx.xx)
	Moderate	10-14	xxxx(xx.xx)	xxxx(xx.xx)
	Severe	>=15	xxxx(xx.xx)	xxxx(xx.xx)

N=Total no of patients in particular visit. *n*=No. of patients in particular category Patient is counted only once in either category.

Table 7c: Summary of Patients who are Screened positive by ASHAs.

	Baseline(N=xxxxx)	Post Intervention(N=xxxxx)
	N(%)	N(%)
Depression Score >=10	xxx (xx.xx)	xxx (xx.xx)
Anxiety Score >=10	xxx (xx.xx)	xxx (xx.xx)
Suicide risk Score >=1	xxx (xx.xx)	xxx (xx.xx)
Anxiety or Depression Score >=10	xxx (xx.xx)	xxx (xx.xx)

N=Total no. of patients who are screened positives. Percentages are calculated based on patients who were screened positive.

		·	Anxiety					Depression			
Screened by	Visit	Ν	Mean (SD)	Midian	Min, Max	P-value	Ν	Mean (SD)	Midian	Min, Max	P-value
ASHA	Baseline	xxxxx	xx.xx (x.xxx)	xx.xx	xx.x, xx.x		xxxxx	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	
	Post Intervention	XXXXX	xx.xx (x.xxx)	XX.XX	xx.x, xx.x		XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	
	Difference	XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	0.xxx	XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	0.xxx
Interviewer	Baseline	xxxxx	xx.xx (x.xxx)	xx.xx	xx.x, xx.x		xxxxx	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	
	Post Intervention	XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x		XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	
	Difference	XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	0.xxx	XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	0.xxx

Table 8a: Change in Depression/Anxiety Score from Baseline to Post Intervention in screen positive

Table 8b: <u>Change in Depression/Anxiety Score from Baseline to Post Intervention for those who had a score >=10 at the beginning of the intervention as screened by ASHAs</u>

Anxiety						Depression					
Visit	Ν	Mean (SD)	Midian	Min, Max	P-value	Ν	Mean (SD)	Midian	Min, Max	P-value	
Baseline	XXXXX	xx.xx (x.xxx)	XX.XX	xx.x, xx.x		XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x		
Post Intervention	XXXXX	xx.xx (x.xxx)	XX.XX	xx.x, xx.x		XXXXX	xx.xx (x.xxx)	XX.XX	xx.x, xx.x		
Difference	XXXXX	xx.xx (x.xxx)	xx.xx	xx.x, xx.x	0.xxxx	XXXXX	xx.xx (x.xxx)	XX.XX	xx.x, xx.x	0.xxxx	

Table 9a: Summary of stressful question for the Patients who are Screened Positive by ASHA

Questions	N=(xx) n(%)
Did you get married in the last 1 year?	xxx (xx.xx)
Did you get separated/divorced in the last 1 year?	xxx (xx.xx)
Did your spouse die in the last 1 year?	xxx (xx.xx)
Did any of your loved ones die in the last 1 year?	xxx (xx.xx)
Did you have a baby in the last 1 year?	xxx (xx.xx)
Did you lose your job in the last 1 year?	xxx (xx.xx)
Did you retire in the last 1 year?	xxx (xx.xx)
Did you or your loved one suffer any major illness/injury in the last 1 year?	xxx (xx.xx)
Did you have any problems with your boyfriend/girlfriend in the last 1 year?	xxx (xx.xx)
Did you have any major problems with your school/college performance in the	
last 1 year?	xxx (xx.xx)
Did you have any major financial problems in the last year?	xxx (xx.xx)
Did you face any natural disaster or stolen livestock or death of livestock, or crop	
failure or forced migration leading to loss of income or property?	xxx (xx.xx)
Did you experience any major crime or were a victim of a major crime like	
robbery, assault/beating, murder/attempted murder, sexual violence?	xxx (xx.xx)

N=Total no. of screen positive patients. *n*=No. of patients in particular category

Table 9b: Summary of stressful events among the Patients who have Depression or Anxiety Score >=10 The shell of table 10b will be exact similar to Table 10a.

Number of Stressful events	(N=xxxx) n(%)
0	xxx (xx.xx)
1	xxx (xx.xx)
2-3	xxx (xx.xx)
>=4	xxx (xx.xx)
Descriptive Statistics (Patients who have total score greater than 1)	
Ν	хххх
Mean (SD)	x.xx (x.xxx)
Median	x.xx
Min, Max	х, х

Table 10: Summary of Stressful Events for the Patients who are Screened Positive by ASHA

N=Total no. of patients in Baseline; n=No. of patients in particular category

Table 11: Summary of Sharing Personal Problems for the Patients who are Screened Positive by ASHA

	(N=xxxx)
	n(%)
When you have a personal problem do you share it with anyone?	xx(xx.xx%)

N=Total no. of patients in Baseline; n=No. of patients in particular category

Question	Baseline (N=xxxxx) n (%)	Post Intervention (N=xxxxx) n (%)
Tobacco products (cigarettes, bidi, gutka, cigars, etc.)	xxx (xx.xx)	xxx (xx.xx)
Alcoholic beverages (beer, wine, spirits, etc.)	xxx (xx.xx)	xxx (xx.xx)
Cannabis (marijuana, pot, grass, hash, etc.)	xxx (xx.xx)	xxx (xx.xx)
Cocaine (coke, crack, etc.)	xxx (xx.xx)	xxx (xx.xx)
Opioids (heroin, morphine, methadone, codeine, etc.)	xxx (xx.xx)	xxx (xx.xx)
Amphetamine type stimulants (speed, diet pills, ecstasy,	xxx (xx.xx)	xxx (xx.xx)
nhalants (nitrous, glue, petrol, paint thinner, etc.)	xxx (xx.xx)	xxx (xx.xx)
Sedatives or Sleeping Pills (Valium, Serepax, Rohypnol,	xxx (xx.xx)	xxx (xx.xx)
Hallucinogens (LSD, acid, mushrooms, PCP, Special K, etc.)	xxx (xx.xx)	xxx (xx.xx)
Other - specify:	xxx (xx.xx)	xxx (xx.xx)

Table 12: Summary of Assessment of Alcohol and Substance Use for the ASHA screened positive Patients

N=Total no. of patients in Baseline; n=No. of patients in particular category

Table 13: Summary of Past History of the ASHA screened positive Patients

Question	Baseline (N=xxxxx) n (%)
Have you ever been told by a health provider that you have heart attack or angina?	(xx.xx) xxx
Have you ever been told by a doctor that you have or had Stroke?	(xx.xx) xxx
Have you ever been told by a doctor that you have or have had Diabetes?	(xx.xx) xxx
Have you ever been told by a doctor that you have or have had Cancer?	(xx.xx) xxx
Have you ever been diagnosed to have any mental disorder?	(xx.xx) xxx
Did you get treated for that mental disorder?	(xx.xx) xxx

N=Total no. of patients in Baseline; n=No. of patients in particular category Percentages for (Did you get treated for that mental disorder?) Is calculated on number of patients diagnosed for mental disorder.

Table 14a: Summary of treatment History among ASHA screened positive Patients

Question	Baseline(N=xxxx)
	n(%)
Are you currently taking any western medicines regularly?	xx(xx.xx)
Are you currently taking any medicines for mental disorders regularly?	xx(xx.xx)

N=Total no. of patients in Baseline; n=No. of patients in particular category

Table 14b: Summary of treatment History during intervention among ASHA screened positive Patients

Question	Baseline(N=xxxx)	
	n(%)	
Did you get treated for your mental health condition as indicated by ASHA/Interviewer	xx(xx.xx)	

N=Total no. of patients in Baseline; n=No. of patients in particular category

Table 14c: Summary of treatment compliance among treated patients of ASHA screened positive

Question	Baseline(N=xxxx)
	n(%)
Did you take medicines as prescribed by the primary care doctor on a regular basis?	xx(xx.xx)

N=Total no. of patients in Baseline; n=No. of patients in particular category

Table 15: Summary of for Utilization of Health Services for Screen Positive subjects

Screen Positive	Health Service used **	Baseline (N=xxxxx) n (%)	Post Intervention (N=xxxxx) n (%)	P-value
By ASHA	Yes	xxx (xx.xx)	xxx (xx.xx)	0.xxxx
	No	xxx (xx.xx)	xxx (xx.xx)	
By Interviewer*	No	xxx (xx.xx)	xxx (xx.xx)	0.xxxx
	Yes	xxx (xx.xx)	xxx (xx.xx)	

* This includes only those patients who were screen positive by Study Interviewer but not by ASHA.

** Health Service used: At baseline: Response from the question "Did you get treated for that mental disorder?" At Post Intervention: Response from the question "Did you get treated for your mental health condition as indicated by ASHA/Interviewer?" P-Value is calculated based on Mc-nimar test for matched pair test of proportion. Table 16a: Case control analysis of Change in Depression/Anxiety Score from Baseline to Post Intervention for those who had a score >=10 at the beginning of the intervention.

Category	Туре	Statistics	Baseline	Post Intervention	Change	P-Value for difference
Anxiety	Cases	Ν	XXXXX	XXXXX	XXXXX	
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
		Median	XX.X	XX.X	XX.X	
		Min, Max	xx; xx	xx; xx	xx; xx	
	Control	Ν	XXXXX	XXXXX	XXXXX	
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	0.xxxx
		Median	XX.X	XX.X	XX.X	
		Min, Max	xx; xx	xx; xx	xx; xx	
Depression	Cases	Ν	XXXXX	ххххх	ххххх	
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	
		Median	XX.X	XX.X	XX.X	
		Min, Max	xx; xx	xx; xx	xx; xx	
	Control	Ν	XXXXX	XXXXX	XXXXX	
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)	0.xxxx
		Median	XX.X	XX.X	xx.x	
		Min, Max	xx; xx	xx; xx	xx; xx	

* Case: The subjects who are screen positive by ASHA.

** Control: The subjects who are screened negative by ASHA but positive by study interviewer.

P-Value is calculated based chi-square independent sample test of proportion.

Table 16b: Case control analysis for health service utilization

Proportion of subject used health services

Category	Baseline	Post Intervention	P-Value
Case*	XXXX	XXXX	
Control**	хххх	XXXX	0.xxx

Health Service used: At baseline: Response from the question "Did you get treated for that mental disorder?"

At Post Intervention: Response from the question "Did you get treated for your mental health condition as indicated by ASHA/Interviewer?"

- * Case: The subjects who are screen positive by ASHA.
- ** Control: The subjects who are screened negative by ASHA but positive by study interviewer.

P-Value is calculated based chi-square independent sample test of proportion.

Table 17: Subject Referrals during ASHA screening

Screened by		(N*=xxxxxx) n(%)
ASHA	Out of those Screened by ASHA Proportion of subject referred to the PHC doctor	xxxx (xx.xx)
	Out of those referred to PHC doctors Proportion of subjects actually visited doctors	xxxx (xx.xx)
	Out of those visited doctors Proportion of subjects appropriately prescribed anti-depressant or anxiolytic Out of those visited doctors Proportion of subjects appropriately referred by the PHC doctor for more	xxxx (xx.xx) xxxx (xx.xx)

*N= overall population screened by ASHAs.