

# **APPENDICES**

## **APPENDIX I (i)**

### **INFORMED CONSENT FORM**

Authorization to participate in research project entitled: “Vitamin B12 and Omega-3 fatty acid Interventions for Cognition in Elderly- a V.O.I.C.E. trial”.

#### **Monitoring Elderly Cognitive Health:**

Neurodegenerative diseases are widely increasing among the elderly. The cure lies in early diagnosis before dementia and Alzheimer’s disease result in progressive cognitive decline. The present study is thus being conducted in my setting, as a part of the Doctoral study of Ms. Aditika Agarwal, Department of Foods and Nutrition, The Maharaja Sayajirao University of Baroda.

The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are invited to take part in this research study because you satisfy our eligibility criteria which are as follow:

- (1) Diagnosis of brain health of elderly by neurological and psychological assessment using scales like ACE, MMSE, YFPIT and nutritional tool MNA.**
- (2) Age between 60 to 85 years.**
- (3) Should be ready to participate willingly and provide information.**

#### **Purpose of this research:**

Mild Cognitive Impairment (MCI) is characterized by decrease in brain functioning. It is detected with the symptoms such as forgetfulness, confusion, etc. It mainly affects the older people.

Decrease in brain functioning is caused due to various factors which include deficiency of certain nutrients like vitamin B12 and omega-3 fatty acids as one of the contributing factors.

We have obtained permission from the Institutional Medical Ethics Committee (Department of Foods and Nutrition, Faculty of Family and Community Sciences. The Maharaja Sayajirao University of Baroda, Vadodara).

#### **Possible benefits to other people**

The results of the research may provide benefits to the society in terms of the advancement of medical knowledge and/or therapeutic benefit to future patients with mild cognitive impairment.

## APPENDIX I (ii)

### PATIENT CONSENT FORM

**Title of the study:** “Vitamin B12 and Omega-3 fatty acid Interventions for Cognition in Elderly- a V.O.I.C.E. trial”.

**Name of the participant:** \_\_\_\_\_

**Name of the guide:** Dr. Komal Chauhan

**Name of the institution:** Department of Foods and Nutrition, Faculty of Family and Community Sciences, The Maharaja Sayajirao University of Baroda.

#### Documentation of the informed consent

I, \_\_\_\_\_, have read the information in this form. I was free to ask any questions and they have been answered. I am over 60 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in the “**Vitamin B12 and Omega-3 fatty acid Interventions for Cognition in Elderly- a V.O.I.C.E. trial**”.

- (1) I have read and understood this consent form and the information provided to me.
- (2) I have had the consent document explained to me.
- (3) I have been explained about the nature of the study.
- (4) My rights and responsibilities have been explained to me by the investigator.
- (5) I have been advised about the risks associated with my participation in the study.
- (6) I agree to cooperate with the investigator and I will inform her immediately if I suffer unusual symptoms.
- (7) I have not participated in any research study within the past \_\_\_\_\_ month (s).
- (8) I have not donated blood within the past \_\_\_\_\_ months, and if this study requires any collection of blood sample then I would not object to give.
- (9) I don't have any objection to take the nutrient supplement of vitamin B12 in the form of injections as well as flaxseeds for omega-3 as a part of the intervention.
- (10) I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.
- (11) I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, government agencies and ethics committee. I understand that they may inspect my original records.
- (12) My identity will be kept confidential if my data are publicly presented.
- (13) I have had my questions answered to my satisfaction.

**(14)**

I have decided to be in the research study.

**APPENDIX I (iii)**  
**PATIENT CONSENT FORM**

**For adult participants:**

Name and signature/thumb impression of the participant (or legal representative if participant incompetent):

\_\_\_\_\_ (Name) \_\_\_\_\_ (Signature)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Name and signature of impartial witness (required for illiterate patients):

\_\_\_\_\_ (Name) \_\_\_\_\_ (Signature)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Address and contact number of impartial witness: \_\_\_\_\_

\_\_\_\_\_

Name and signature of the Investigator or his representative obtaining consent:

\_\_\_\_\_ (Name) \_\_\_\_\_ (Signature)

\_\_\_\_\_ (Date)

**Investigator Certificate**

I certify that all the elements including the nature, purpose and possible risks of the above study as described in this consent document have been fully explained to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of the Investigator: \_\_\_\_\_ Dated: \_\_\_\_\_

Name of the Investigator: \_\_\_\_\_

**Contact persons:**

**For further information /questions, you can contact us at the following address:**

**Guide and Investigator: Dr. Komal Chauhan, Phone No. 9898790340**

**PhD Student: Ms. Aditika Agarwal, Phone No. 7600889247**

Department of Foods and Nutrition, Faculty of Family and Community Sciences, The Maharaja Sayajirao University of Baroda.

## APPENDIX II

### GUJARATI CONSENT FORM

ભાગ લેનાર માટે માહિતી અને સંમતિ પત્રક

આ સંશોધન અભ્યાસમાં ભાગ લેવા માટે તમને આમંત્રણ છે. આ દસ્તાવેજમાં આપેલી માહિતી તમને ભાગ લેવો કે નહિ તે નક્કી કરવામાં મદદરૂપ થશે. તમને કોઈ શંકા અથવા પ્રશ્નો હોય તો સંકોચે પૂછશો.

મહારાજા સયાજીરાવ યુનિવર્સિટી ઓફ બરોડાની ફેકલ્ટી ઓફ ફેમિલી એન્ડ કોમ્યુનિટી સાયન્સીસના ફુડ એન્ડ ન્યુટ્રીશન વિભાગ દ્વારા આયોજીત આ અભ્યાસ માટે તમને ભાગ લેવાનું કહેવામાં આવે છે કારણ કે તમે નીચેની લાયકાત સંતાપો છો.

૧. મીની મેન્ટલ સ્ટેટ એક્ઝામીનેશન દ્વારા માનસીક સ્વાસ્થ્યનું નિદાન.
૨. ઉંમર ૬૦ થી ૮૫ વર્ષની વચ્ચે
૩. ઈચ્છાથી ભાગ લઈશ અને માહિતી આપીશ.

આ સંશોધનનો હેતુ :

માનસીક સ્વાસ્થ્ય ઓછું થવું, એ કોગનીટીવ ઈમ્પેરમેન્ટ નું મુખ્ય લક્ષણ છે. મુઝવણ, હતાશા, ભુલી જવો વગેરે આના સામાન્ય લક્ષણો છે. જે મુખ્યત્વે મોટી ઉંમરના લોકોને લાગું પડે છે. માત્ર બે ટકા જેટલા લોકોને ૬૫ વર્ષ પહેલાં આ શરૂ થાય છે.

ઘણાં બધા તત્વો માનસીક સ્વાસ્થ્ય ઘટાડવા માટે જવાબદાર છે. જેમાં પોષણ તત્વોની ઉણપ મુખ્યત્વે વિટામીન -બી ૧૨ એ મહત્વનો ભાગ ભજવે છે.

અત્યારે આની સારવાર તરીકે વિટામીન -બી ૧૨ ની વધારાની પુરવણી સામેલ કરવામાં આવી છે.

બીજા લોકોને ફાયદાની શક્યતા :

આ સંશોધનના પરિણામોથી સમાજને ગિકિત્સા વિજ્ઞાનની પ્રગતિના લાભ મળી શકે અને / અથવા કોગનીટીવ ઈમ્પેરમેન્ટથી પીડિત વ્યક્તિઓ ને વધુ સારી સારવાર મળી શકે.

## સંમતિ પત્ર

અભ્યાસનું શિર્ષક : “મોટી ઉંમરના બહેનોના કોગનીટીવ ઇમ્પેરમેન્ટના વિટામીન -બી ૧૨ ની અસર : માનસીક સ્વાસ્થ્યને લગતી બીમારીઓને સંદર્ભમાં વડોદરાના શહેરી વિસ્તારના મોટી ઉંમરના લોકોની જીવન ચર્ચા, પોષણ ક્ષમ સ્થિતિ અને આહાર વલણ અંગેનો વલણ અને જુદા-જુદા રોગો અંગેની સ્થિતિ નું મુલ્યાંકન.”

ભાગ લેનારનું નામ :

મુખ્ય સંશોધકનું નામ : ડૉ. કોમલ ચૌહાણ

સંસ્થાનું નામ : ફુડ એન્ડ ન્યુટ્રીશન વિભાગ, ફેકલ્ટી ઓફ ફેમીલી એન્ડ કોમ્યુનીટી સાયન્સીસ, મહારાજા સયાજીરાવ યુનિવર્સિટી ઓફ બરોડા, વડોદરા.

સહાયક (ફાળો આપનારી સંસ્થાઓ ના નામ અને સરનામા ) :

માહિતગારની સંમતિની નોંધ

મેં. \_\_\_\_\_ આ પત્રકમાં આપેલી માહિતી વાંચી છે. મને કોઈ પણ પ્રશ્ન પૂછવાની છૂટ હતી અને એના જવાબો મળ્યા છે. મારી ઉંમર ૬૦ વર્ષથી ઉપર છે અને પસંદગી કરવાની મારા મુદત અધિકારનો ઉપયોગ કરીને આ ઉપર બતાવેલા શિર્ષકવાળા અભ્યાસમાં ભાગ લેનાર તરીકે મને સામેલ કરવા માટે હું મારી સંમતિ આપું છું.

૧. મેં આ સંમતિપત્ર અને મને પૂરી પાડવામાં આવેલી માહિતી વાંચી છે. અને સમજ્યો છું.
૨. સંમતિ દસ્તાવેજ વિષે સમજ આપવામાં આવી છે.
૩. મને આ અભ્યાસનું સ્વરૂપ સમજાવવામાં આવ્યું છે.
૪. શોધકર્તા દ્વારા અને મારા હકકો અને જવાબદારીઓ વિષે સમજાવવામાં આવ્યું છે.
૫. આ અભ્યાસમાં મારા ભાગ લેવા સાથે જોડાયેલા જોખમો વિશે મને સલાહ આપવામાં આવી છે.
૬. હું મારા શોધકર્તા ને સહકાર આપવા કબુલ થાઉં છું અને મને કોઈ પ્રકારના અસ્વાભાવિક લક્ષણો જણાય તો તરત જ તેમણે જાણ કરીશ.
૭. મેં છેલ્લા \_\_\_\_\_ મહિનાઓ દરમિયાન કોઈ સંશોધન અભ્યાસમાં ભાગ લીધો નથી.

- મહિનાઓ દરમિયાન રક્તદાન કરેલું નથી અને આ
૯. મેં જોયું અભ્યાસ દરમિયાન લોહીના નમૂના લેવાની જરૂરીયાત ઊભી થાય તો તે આપવા માટે હું વિશેષ નહીં કરું.
  ૧૦. પ્રયોગના ભાગરૂપે ઈન્જેક્શનના સ્વરૂપે અથવા ટીક્કીના સ્વરૂપે વીટામીન બી ૧૨ ની ખોજક પૂરવણી લેવામાં મને કોઈ વાંધો નહીં.
  ૧૧. શોધકર્તા મેં ત્યારે, કોઈ પણ કારણ થી મારી સંમતિ વગર આ અભ્યાસમાં મારી ભાગીદારીનો મારી ભાગીદારીનો અંત લાવી શકે છે તે બાબત હું સભાન છું.
  ૧૨. મારી ભાગીદારી ના પરિણામ સ્વરૂપ મારી પાસેથી મળેલી માહિતી નોધકર્તાઓ પ્રોત્સાહકોને, નિયામક અધિકારીઓને, સરકારી વિભાગોને કે એથીક્સ કમિટીને આપી શકે તે માટે હું પરવાનગી આપું છું. હું સમજું છું કે તેઓ મારા મૂળભૂત દસ્તાવેજો તપાસી શકે છે.
  ૧૩. મારી આપેલી વિગતોની જાહેરમાં પ્રસિદ્ધિ કરવામાં આવે તો મારી ઓળખ ખાનગી રાખવામાં આવશે.
  ૧૪. મેં પૂછેલા પ્રશ્નોના મને સંતોષકારક જવાબો મળ્યા છે.
  ૧૫. મેં આ સંશોધન અભ્યાસમાં જોડાવવાનું નક્કી કરી લીધું છે.

પુખ્ત વયના ભાગ લેનાર માટે

ભાગલેનાર (અથવા ભાગલેનાર અસમર્થ હોય તો તેના અધિકૃત પ્રતિનિધિ) નું નામ અને સહી / સંમુદયનું નિશાન

\_\_\_\_\_ નામ \_\_\_\_\_ સહી  
તારીખ \_\_\_\_\_ સમય \_\_\_\_\_

ભાગ લેનાર નિરક્ષર હોય તો) તટસ્થ સાક્ષીનું નામ અને સહી

\_\_\_\_\_ નામ \_\_\_\_\_ સહી  
તારીખ \_\_\_\_\_ સમય \_\_\_\_\_

સાક્ષી નું સરનામું અને સંપર્ક નંબર \_\_\_\_\_

સંમતિ મેળવનાર શોધકર્તા અથવા તેના પ્રતિનિધિનું નામ અને સહી

\_\_\_\_\_ નામ \_\_\_\_\_ સહી  
તારીખ \_\_\_\_\_ સમય \_\_\_\_\_

## શોધકર્તાનું પ્રમાણ પત્ર

હું પ્રમાણપત્ર આપું છું કે આ સંમતિ પત્ર માં વર્ણવેલા આગળ જણાવેલ અભ્યાસને લગતી બધી બાબતો, જેમ કે એનું બંધારણ, હેતુ અને સંભવિત જોખમો વિગેરે બધું જ વ્યક્તિને સંપૂર્ણ રીતે સમજાવવામાં આવેલું છે. મારી ધારણા મુજબ ભાગલેનાર વ્યક્તિ આ સંશોધનમાં ભાગલેવા માટે અધિકૃત ક્ષમતા ધરાવે છે. અને પોતે મરજીયાત પછે અને સમજદારીપૂર્વક ભાગ લેવા માટે સંમતિ આપે છે.

શોધકર્તા ની સહી : \_\_\_\_\_

તારીખ : \_\_\_\_\_

શોધકર્તા નું નામ : \_\_\_\_\_

સંપર્ક વ્યક્તિઓ : \_\_\_\_\_

વધુ માહિતી પ્રશ્નો માટે નીચેના સરનામે સંપર્ક કરી શકો છો.

ડૉ. કોમલ ચૌહાણ

મો. નં. 9898790340

અદીતીકા અગ્રવાલ

મો. નં. 7600889247



# APPENDIX III

## ADDENBROOKE'S COGNITIVE EXAMINATION - ACE-R Hindi Version (2006) NIMS Hyderabad

Name: \_\_\_\_\_  
Age: \_\_\_\_\_ Sex: \_\_\_\_\_  
Date of testing: \_\_\_\_\_  
Tester's Name: \_\_\_\_\_  
Years of education: \_\_\_\_\_  
Occupation: \_\_\_\_\_  
Handedness: \_\_\_\_\_

दिन	तारीख	महीना	साल	मौसम	[ Score 0-5 ] [ ] [ ]
मौसम	मौसम	मौसम	मौसम	मौसम	[ Score 0-5 ] [ ] [ ]

**PERCEPTION**  
आपको तीन शब्द बताएंगे। वो आप द्वारा मुझे बताइए। नींबू, चाव्री, गेंद After subject repeats, say  
इसे याद रखिए। बाद में दुबारा पूछूंगा। Score only the first trial ( repeat 3 times if necessary )  
Register number of trials: \_\_\_\_\_ [ Score 0-3 ]  
[ ] [ ]

**ATTENTION/CONCENTRATION**  
पूछिए : मैं ग से याद लिखाऊँगा। After the Subject responds, ask him or her to take away another 7 to a total of 5 subtractions. If Subject makes a mistake, carry on and check the subsequent answer (i.e. 93, 84, 77, 70, 63-Score 4)  
Stop after five subtractions ( 93, 86, 79, 72, 65 )  
पूछिए : 'समालोचना' इस शब्द को उलटके बताइए। [ Score 0-5 ]  
[ ] [ ]  
(For the best performed task)

**MEMORY - Recall**  
पूछिए : इससे पहले या तीन शब्द याद रखने को बोले थे, वो बताइए। [ Score 0-3 ]  
[ ] [ ]

**MEMORY - Anterograde Memory**  
बताइए : अब मैं आपको एक आदमी का नाम और पता बताता हूँ। आप दुबारा मुझे बताइए।  
तीन बार बताता हूँ ताकी आप याद रख सकें। थोड़ी देर बाद फिर से पूछूंगा। [ Score 0-7 ]  
[ ]  
Score only the third trial.

	1 <sup>st</sup> Trail	2 <sup>nd</sup> Trail	3 <sup>rd</sup> Trail
विष्णु मंदिर :	.....	.....	.....
राम मंदिर :	.....	.....	.....
नगर :	.....	.....	.....
राज्य :	.....	.....	.....

**MEMORY - Retrograde Memory**  
इस प्रदेश के प्रस्तुत मुख्यमंत्री का नाम बताइए।  
अपने देश की जो महिला प्रधानमंत्री थी, उनका नाम बताइए।  
मेरा नाम जोकर फिल्म के हीरो का नाम बताइए।  
अपने राष्ट्र पिता का नाम बताइए। [ Score 0-4 ]  
[ ]

ATTENTION & ORIENTATION  
Y  
R  
O  
M  
E  
M  
O  
R  
Y

# MAXIMUM COGNITIVE EXAMINATION: ACE-R GENERAL FLUENCY- Letter 'P' and animals

**Letters**  
 बताइए : मैं आपको एक अक्षर बताता हूँ। उस अक्षर से शुरू होनेवाले शब्द आप जितने बता सकते हैं, उतने बताइए । [Score 0-7]  
 इसका नाम और जगह के नाम नहीं होने चाहिए । आपको एक मिनट का वक्त देता हूँ । वो अक्षर है  
 'प' (पि, पु, पे, पो... जैसे 'प' की बाराखडी में से किसी भी अक्षर से बता सकते हैं) ।

					>17	7
					14-17	6
					11-13	5
					8-10	4
					6-7	3
					4-5	2
					2-3	1
					<2	0
					total	Correct

**Animals**  
 बताइए : अब आप जितने जानवरों के नाम बता सकते हैं उतने बताइए । किसी भी अक्षर से शुरू हो सकता है । [Score 0-7]

					>21	7
					17-21	6
					14-16	5
					11-13	4
					9-10	3
					7-8	2
					5-6	1
					<5	0
					total	Correct

## LANGUAGE-Comprehension

Show written instruction

[Score 0-1]

' आँखे बन्द कीजिए '

3 Steps command

इस कागज को अपने दाँए हाथ में लीजिए । कागज को आधा मोड़िए । इसे ज़मीन पर रखिए ।

[Score 0-3]

## LANGUAGE-Writing

पूछिए : नीचे दिए गये जगह में कोयी भी एक वाक्य लिखिए ।

Score 1 if sentence contains a subject and a verb (see guide for examples)


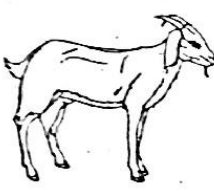
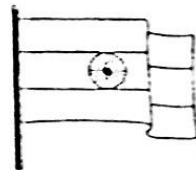



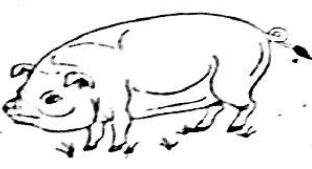

[Score 0-1]

Y  
O  
Z  
E  
J  
L  
F  
E  
G  
A  
J  
G  
N  
A  
L

1. इन शब्दों को सुकरा बनाएँ ।  
 सुकरा : 'राष्ट्रपति' ; 'आदमी' ; 'शताब्द' ;  
 2. इन शब्दों को सुकरा बनाएँ ।  
 सुकरा : 'आदमी' ; 'शताब्द' ;  
 3. इन शब्दों को सुकरा बनाएँ ।  
 सुकरा : 'आदमी' ; 'शताब्द' ;  
 4. इन शब्दों को सुकरा बनाएँ ।  
 सुकरा : 'आदमी' ; 'शताब्द' ;

[ Score 0-2 ]  
  
 [ Score 0-1 ]  
  
 [ Score 0-1 ]

5. निम्नलिखित चित्रों के नाम बताएँ ।

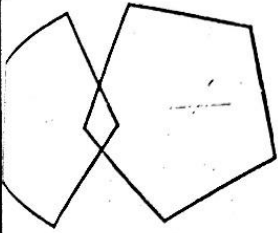
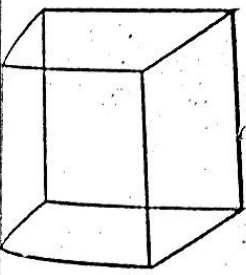
	
	
	
	

[ Score 0-2 ]  
 pencil+  
 watch  
   
 [ Score 0-10 ]

6. Comprehension  
 निम्न दिए गए चित्रों के आधार पर इन बातों को पूरिए ।  
 1. कौन सा जानवर घास खाता है ?  
 2. कौन सा जानवर पानी पीता है ?  
 3. कौन सा जानवर घास खाता है ?  
 4. कौन सा जानवर पानी पीता है ?

[ Score 0-4 ]

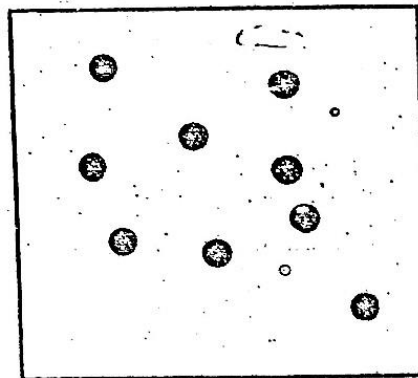
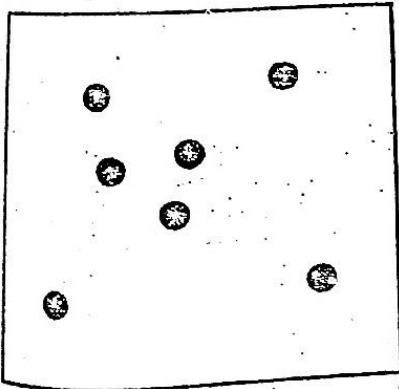
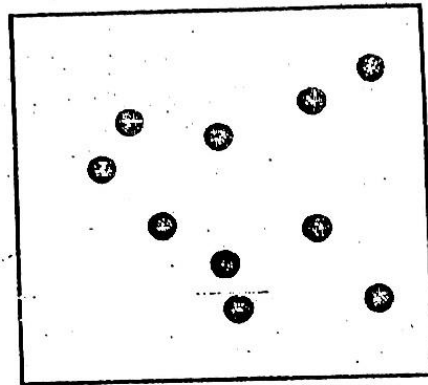
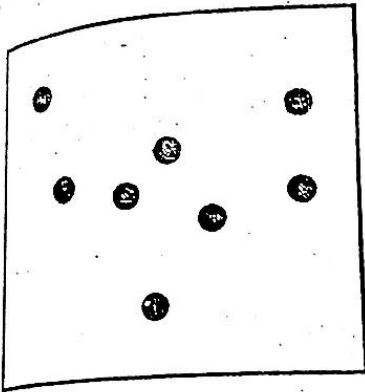
L A N G U A G E

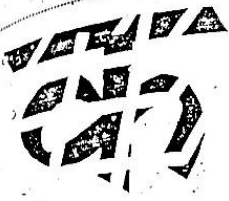
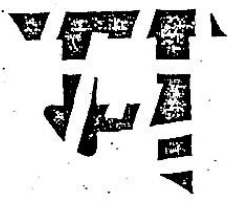


WISC-III COGNITIVE EXAMINATION - AGE-R		LANGUAGE	
<p>निम्नलिखित शब्दों को पहचानिए ।</p> <p>समुच्चय प्राग्भ क्लेश महर्षि अकांक्षा</p> <p>[score 1 only if all correct]</p>		<p>[Score 0-1]</p> <p><input type="text"/></p>	
<p>SPATIAL ABILITIES</p> <p>पृष्ठिणः इन चित्र को देखकर बनाइए ।</p> 		<p>[Score 0-1]</p> <p><input type="text"/></p>	
<p>गुणः इन चित्र को देखकर बनाइए । [for scoring see instructions guide]</p> 		<p>[Score 0-2]</p> <p><input type="text"/></p>	
<p>पृष्ठिणः पाँच बजकर दस मिनट दिखाती हुई घड़ी बनाइए ।</p> <p>[for scoring see instructions guide, circle=1, numbers=2, hands=2 if all correct]</p>		<p>[Score 0-5]</p> <p><input type="text"/></p>	

V I S U O S P A T I A L

पूछिए : नीचे दिये गए बिन्दुओं को बिना उंगली लगाए गिनिये ।

[ Score 0-1 ]




ADJENBROOKE'S COGNITIVE EXAMINATION - ACE-R				(Score 0-4)	
PERCEPTUAL ABILITIES				[ ]	
<p>पूछिए : इन अक्षरों को पहचानिए ।</p>					
				V I S U O S P A T I A L	
<p>RECALL</p>					
<p>पूछिए : हमने जो आदमी का नाम और पता पहले बताया था, जो याद करके बताइए ।</p>					
<p>सुनीलकुमार सिंह .....          42, स्टेशनरोड .....          गांधीनगर, .....          इलाहाबाद .....</p>				(Score 0-7) [ ]	
<p>RECOGNITION</p>					
<p>This test should be done if subject failed to recall one or more items. If all items were recalled, skip the test and score 5. If only part is recalled, start by ticking items recalled in the shadowed column on the right hand side. Then, Test not recalled items by telling अब मैं आप को कुछ नाम बताता हूँ । उन्मे से मेरा पहला बताया हुआ नाम पहचानिये and so on. Each recognized item scores one point which is added to the point gained by recalling.</p>					
रमेश शर्मा 25 ट रोड शनगर बाद	सुनीलकुमार सिंह 52 शास्त्री मार्ग गांधीनगर मवालयर	राकेश यादव 37 स्टेशन रोड पटेलनगर इन्दौर	recalled recalled recalled recalled recalled	(Score 0-5) [ ]	
<p>Scores</p>					
MMSE				/30	
ACE-R				/100	
<p>es</p>					
Attention & Orientation				/18	
Memory				/26	
Fluency				/14	
Language				/26	
Visuo Spatial				/16	
SCORE				SCORE	

## APPENDIX IV (ii)

### MINI NUTRITIONAL ASSESSMENT (MNA)

# Mini Nutritional Assessment

## MNA<sup>®</sup>



Last name:		First name:		
Sex:	Age:	Weight, kg:	Height, cm:	Date:

Complete the screen by filling in the boxes with the appropriate numbers. Total the numbers for the final screening score.

Screening	
<b>A</b> Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties? 0 = severe decrease in food intake 1 = moderate decrease in food intake 2 = no decrease in food intake	<input type="checkbox"/>
<b>B</b> Weight loss during the last 3 months 0 = weight loss greater than 3 kg (6.6 lbs) 1 = does not know 2 = weight loss between 1 and 3 kg (2.2 and 6.6 lbs) 3 = no weight loss	<input type="checkbox"/>
<b>C</b> Mobility 0 = bed or chair bound 1 = able to get out of bed / chair but does not go out 2 = goes out	<input type="checkbox"/>
<b>D</b> Has suffered psychological stress or acute disease in the past 3 months? 0 = yes      2 = no	<input type="checkbox"/>
<b>E</b> Neuropsychological problems 0 = severe dementia or depression 1 = mild dementia 2 = no psychological problems	<input type="checkbox"/>
<b>F1</b> Body Mass Index (BMI) (weight in kg) / (height in m <sup>2</sup> ) 0 = BMI less than 19 1 = BMI 19 to less than 21 2 = BMI 21 to less than 23 3 = BMI 23 or greater	<input type="checkbox"/>
IF BMI IS NOT AVAILABLE, REPLACE QUESTION F1 WITH QUESTION F2. DO NOT ANSWER QUESTION F2 IF QUESTION F1 IS ALREADY COMPLETED.	
<b>F2</b> Calf circumference (CC) in cm 0 = CC less than 31 3 = CC 31 or greater	<input type="checkbox"/>
<b>Screening score</b> (max. 14 points)	<input type="text"/> <input type="text"/>
<b>12-14 points:</b> Normal nutritional status <b>8-11 points:</b> At risk of malnutrition <b>0-7 points:</b> Malnourished	

Ref. Velaz B, Villar M, Abellan G, et al. Overview of the MNA® - its history and Challenges. J Nutr Health Aging 2006; 10:466-468.

Rubenstien LZ, Harker JO, Salva A, Guigoz Y, Velaz B. Screening for Undernutrition in Geriatric Practice: Developing the Short-Form Mini Nutritional Assessment (MNA-SF). J Geront 2001;56A: M366-377.

Guigoz Y. The Mini-Nutritional Assessment (MNA®) Review of the Literature - What does it tell us? J Nutr Health Aging 2006; 10:466-467.

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For more information: [www.mna-elderly.com](http://www.mna-elderly.com)

## APPENDIX V

### QUESTIONNAIRE

#### A. SOCIO-ECONOMIC SURVEY

ID No: \_\_\_\_\_

Date: \_\_\_\_\_

1) Name: \_\_\_\_\_

2) Address: \_\_\_\_\_

Phone No: \_\_\_\_\_

3) Date of Birth: \_\_\_\_\_

4) Age (in years): \_\_\_\_\_

5) Marital status: \_\_\_\_\_

1) Unmarried 2) Married 3) Widow/Widower 4) Separated

☐

6) Education Level: \_\_\_\_\_

1) Post graduation 2.) Graduation 3) High Secondary School  
4) Secondary school 5) Primary School 6) Illiterate

☐

7) Occupation: \_\_\_\_\_

1) Service 2) Self Employed 3) Housewife 4) Retired

☐

8) Religion: \_\_\_\_\_

1) Hindu 2) Muslim 3) Christian 4) Jain 5) Other

☐

9) Type of family: \_\_\_\_\_

1) Nuclear 2) Joint 3) Extended 4) Single living

☐

10) No. of family members: \_\_\_\_\_

11) Total family income (Rs.per month): \_\_\_\_\_

1) < 10,000 2) 10001-30000 3) 30001-60000 4) 60001-100000 5) > 100000

☐

12) Per capita income: \_\_\_\_\_

13) Care taker of the subject: \_\_\_\_\_

1) Family member 2) Spouse 3) Self 4) Institution/trust 5) Any other

☐

#### B. LIFE STYLE PATTERN

##### 14) ACTIVITIES OF DAILY LIVING

Activities	Time spent in hours
1.Daily routine	
2.Religious	
3.Sleep	
4.Exercise	
5.Walk	
6.Occupational activity	
7.Idle	



### 15) ADDICTION PATTERN

Addiction	Yes	No	Age of initiation (in years)
1.Cigarette/Bidi			
2.Alcohol			
3.Tobacco/Gutkha			

### C. ANTHROPOMETRIC MEASUREMENTS

1) Weight: \_\_\_\_\_ kgs                      3) WC: \_\_\_\_\_ cms.

2) Height: \_\_\_\_\_ cms                      4) HC: \_\_\_\_\_ cms.

### D. BIO-PHYSICAL PARAMETER

1) Blood pressure \_\_\_\_\_ mmHg

### E. BIO-CHEMICAL PARAMETERS

1) Blood glucose \_\_\_\_\_ mg/dl    3)Serum vitamin B12 \_\_\_\_\_ pg/ml

2)Hemoglobin \_\_\_\_\_ g/dl    4)Serum lipid profile \_\_\_\_\_ mg/dl

### F. DIETARY SURVEY

16) Are you vegetarian/non-vegetarian/eggetarian?

☐

17) How much of water do you consume daily? 1) < 5 glasses 2) 6-8 glasses  
3) > 8 glasses

☐

18) A. Do you observe fast? 1) Yes    2) No

☐

B. If yes, how often? 1)1/wk    2)Twice a week    3)Occasionally

☐

19) No. of meals per day: \_\_\_\_\_

20) Food Frequency Questionnaire of Selected Sources

FOOD ITEMS	Daily	2-3 times/wk	4-5 times /wk	Once a week	Occasionally	Never
<b>Vitamin B-12 rich</b>						
1.Skim Milk Powder						
2.Milk						
3.Curd						
4.Egg ,whole						
5.Egg ,yolk						
6.Shrimp						
7.Liver, goat						
8.Mutton						
<b>Omega-3 Rich</b>						



23) A. Are you taking any kind of supplements? 1) Yes 2) No

B. If yes, give details. \_\_\_\_\_

☐

24) A. Changes in Food Consumption 1) Yes 2) No

B. If yes, specify what you have increased/decreased/totally omitted.  
\_\_\_\_\_

25) Have you experienced any changes in your perception of taste? Specify.

Perception of taste	Yes	No	Since when
1. Sweet			
2. Salty			
3. Sour			
4. Bitter			
5. Pungent			

#### E. MORBIDITY PROFILE

26) A. Are you taking any prescription drugs per day? 1) Yes 2) No

B. Name the drug \_\_\_\_\_

27) ILLNESSES (Checklist at the time of interview)

Major Illnesses	1) N	2) Y (Name the disease and since when)	Major Illnesses	1)N	2) Y (Name the disease and since when)
Central Nervous system			Cardiovascular		
Speech problem			Genito –urinary		
Memory loss			Hepato-biliary tract		
Mood/ behavior change			Respiratory Tract		
Convulsive attacks			Oral Cavity		
Difficulty in performing familiar tasks			Gastrointestinal Tract		
Double vision			Endocrinal		
Minor(Ref. period 15 days)	1)N	2) Y			

## HEALTH STATUS

### 28) MINI MENTAL STATUS EXAMINATION (MMSE)

#### A. ORIENTATION (Score 1 if correct)

(10)

1. Name this society/building? \_\_\_\_\_
2. Name the city you are in now? \_\_\_\_\_
3. What year is this? \_\_\_\_\_
4. What month is this? \_\_\_\_\_
5. What is the date today? \_\_\_\_\_
6. Name the state you are in now? \_\_\_\_\_
7. Name the country you are in now? \_\_\_\_\_
8. Which floor of the building are you on? \_\_\_\_\_
9. What day of the week is it? \_\_\_\_\_
10. Which season of the year is it? \_\_\_\_\_

#### B. REGISTRATION

(3)

1. Name 3 objects and have the patient repeat them. Score number repeated by the patient.
2. Name 3 objects several more times if needed for the patient to repeat correctly. (record trials)

#### C. ATTENTION AND CALCULATION

(5)

1. Subtract 7 from 100 in serial fashion to 65 (Max. score 5)

#### D. RECALL

(3)

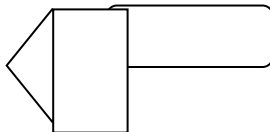
2. Do you recall the 3 objects named before? \_\_\_\_\_

#### E. LANGUAGE TEST

(9)

1. Confrontation naming: Watch, pen \_\_\_\_\_ 2
2. Repetition: "No Ifs, Ands or Buts" \_\_\_\_\_ 1
3. Comprehension: Pick up the paper in your right hand, fold it in half and set it on floor \_\_\_\_\_ 3
4. Read and perform the command: "Close your eyes" \_\_\_\_\_ 1
5. Write any sentence (subject, object, verb) \_\_\_\_\_ 1
6. CONSTRUCTION

Copy the design below



1

**Total MMSE questionnaire score (Max=30)**\_\_\_\_\_

**29) YFPIT score:** 1. Fox \_\_\_\_\_ 2. Pigeon \_\_\_\_\_

## APPENDIX VI

### STANDARD RECIPES OF FOOD PRODUCTS

The standard recipes of the food products (*Khichdi*, *porridge*, *globs* and *mukhwaas*) for formulation and acceptability trials at varying substitution levels of roasted flaxseeds are as follows:

#### I. *Khichdi*

Ingredients	Amount (g)	Volume
Green gram dal (split)	20	1
Rice	20	1/2 cup
Water	200 ml	1 cup
Turmeric	2	-
Groundnut oil	5 ml	1 tsp

#### Preparation Method:

- ▲ Heat oil in pressure cooker. Then add green gram dal and rice previously soaked for about 30 minutes.
- ▲ Stir for a minute pour water and add turmeric. Pressure cook on high flame till 6 whistles.
- ▲ Keep on sim or low flame to simmer the khichdi till the right consistency.

Roasted flaxseeds were substituted at 10g (10g flaxseeds + 20g green gram + 20g rice+5 ml oil), 15 g (15g flaxseeds + 20g green gram + 20g rice+5 ml oil) and 20g (20g flaxseeds + 20g green gram + 20g rice+5 ml oil) levels in *khichdi*.

## II. *Porridge*

Ingredients	Amount (g)	Volume
Gruel wheat	30	2 tbsp
Water	150 ml	1 cup
Sugar	5	1 tsp
Milk	125 ml	1/2 cup

### Preparation Method:

- ▲ Add gruel wheat in a saucepan and roast it on medium low heat for 4 to 5 minutes till it becomes light brown giving off a roasted aroma.
- ▲ Add water and mix with roasted gruel wheat. Partially cover the pan because once gruel wheat starts boiling, the froth starts coming out of the saucepan. Let the gruel cook for 10-12 minutes until tender and water gets absorbed.
- ▲ Add milk and mix and let it cook uncovered until it reaches to desired consistency.
- ▲ Add sugar and simmer for few minutes, then turn the stove off.

Roasted flaxseeds were substituted at 10g (10g flaxseeds + 125 ml milk + 30g gruel wheat + 5 g sugar), 15 g (15g flaxseeds +125 ml milk + 30g gruel wheat + 5 g sugar) and 20g (20g flaxseeds + 125 ml milk + 30g gruel wheat + 5 g sugar) levels in *porridge*.

### III. *Globs*

Ingredients	Amount (g)	Volume
Flaxseeds	20	4 tsp
Water	5ml	1tsp
Jaggery	15	1tsp

#### Preparation Method:

- ▲ The flaxseeds are roasted on medium flame for up to 7 minutes and ground coarsely.
- ▲ The jaggery is then melted in a pan with 5 ml of water and ground flaxseeds are added.
- ▲ The mixture is stirred uniformly for about 2 minutes.
- ▲ Knead the globs until it holds into a ball of mass. Keep kneading until lemon sized balls are rolled out while they were warm for instant binding.

Roasted flaxseeds were substituted at 10g (10 g of flaxseeds with 15 g jaggery), 15 g (15 g flaxseeds with 15 g jaggery) and 20g (20 with 15 g jaggery) levels in *globs*



#### IV. *Mukhwaas*

Ingredients	Amount (g)	Volume
Flaxseeds	20	4 tsp

#### Preparation Method:

- ▲ Dry roast the flaxseeds in a broad pan for 2 to 3 minutes till it starts giving a good aroma.
- ▲ Cool completely and store in an airtight container.

Roasted flaxseeds were substituted only at 20g (20 g of flaxseeds) level in *mukhwaas* after *being* the preferred substitution amount affirmed from the acceptability trials by the semi-trained and untrained panelists

## APPENDIX VII (i)

### THRESHOLD TEST

#### Sensitivity- Threshold Test

Name: \_\_\_\_\_

Date: \_\_\_\_\_

**You are provided with a series of containers having solutions with increasing concentration of one of the taste qualities (sweet, salty). Please start with the Sr. No. 1 and continue with the rest. The samples are not allowed to be retested. Please describe the taste or give intensity scores using the scoring pattern shown separately here below.**

#### Intensity Score

Set No.	Description of taste and feeling factors
A	-
B	-
C	-
D	-
E	-
F	-

Scale:

While awarding the intensity scores, take the following basis into account;

0 - None or taste of pure water

? – Different from water but taste quality not identifiable

x- Threshold very weak (Taste identifiable)

1- Weak taste

2- Medium

3- Strong

4- Very strong

5- Extremely strong

\_\_\_\_\_  
**Signature of the Judge**

## APPENDIX VII (ii)

### THRESHOLD TEST

#### (ii) Procedure for preparation of solution required for threshold test

Solution No.	Molarity	Salty (Stock solution 5.845 g of sodium chloride/L) ml of stock solution to be diluted to 1 L	Sweet (Stock solution 34.23 g of sucrose/L) ml of stock solution to be diluted to 1 L	Molarity	Sour (Stock solution 21.015 g of citric acid/L) ml of stock solution to be diluted to 1 L	Bitter (Stock solution 19.41 g of caffeine/L) ml of stock solution to be diluted to 1 L
1	0.0002	2	2	0.0005	0.5	0.5
2	0.0004	4	4	0.0001	1	1
3-	0.0008/	8	8	0.0002	2	2
4	0.0016	16	16	0.0004	4	4
5/	0.0032'	32	32	0.0006	6	6
6	0.0064	64	64	0.0008	8	8
7-	0.0128	128	128	0.0010	10	10
8	0.0256	256	256	0.0012	12	12
9'	0.0512	2.994 g/L	17.526 g/L	0.0014	14	14
10	0.1024	5.988 g/L	35.052 g/L	0.0016	16	16

Source: Jellinek, G. *J Nutr Diet.* 1964; 1:219.

## APPENDIX VI (i)

### HEDONIC SCALE

**Name:**

**Date:**

**Product: Flaxseed Mukhwaas**

**Time:**

You are presented with the sample of Flaxseed Mukhwaas. Test this sample and check (✓) appropriate box how much you like or dislike. Use this appropriate scale to show your attitude by checking at the point that best describes your feeling about the sample. Please give your reason for this attitude.

Sr. No.	Points	Mukhwaas
1.	Like extremely	
2.	Like very much	
3.	Like moderately	
4.	Like slightly	
5.	Neither like nor dislike	
6.	Dislike slightly	
7.	Dislike moderately	
8.	Dislike very much	
9.	Dislike extremely	

Comments / suggestion:

---

Signature

## APPENDIX VI (ii)

### COMPOSITE SCORE CARD

**Name:**

**Date:**

**Product: Flaxseed Mukhwaas**

**Time:**

You are presented with the sample of Flaxseed Mukhwaas. Test this sample by scoring on basis of following attributes. Use this scoring to show your attitude by checking at the point that best describes your feeling about the sample. Please give your comments.

---

Attribute	Total Marks	Sample Score
Taste	20	
Appearance	10	
Odour	10	
Texture	15	
Absence of defects	10	
Suitability of serving (10 gms)	15	
Over all acceptability	20	
<b>TOTAL</b>	<b>100</b>	

---

Comments / suggestions:

\_\_\_\_\_  
Signature



Ref. No. : UHC/

**University Health Centre**  
**The Maharaja Sayajirao University of Baroda**

Opp. Rosary High School, Pratapgunj, Vadodara 390 002, Gujarat, India.  
Tel. : (+91 0265) 2791616

Dated: 27/1/15

**TO WHOM SO EVER IT MAY CONCERN**

This is to certify that Ms. Aditika Agarwal, Research Scholar, Department of Foods and Nutrition, The M.S. University of Baroda has been monitoring the patients for blood pressure determination using the manual sphygmomanometer since January, 2011 for her research work. To the best of my knowledge, she is well acquainted with the instrument and can measure by the pulse tone method also for confirmed diagnosis for blood pressure.

I am glad to approve her and wish her all the best for her endeavours.

  
**I/C. MEDICAL OFFICER**  
**UNIV. HEALTH CENTRE**

DEPARTMENT OF FOODS AND NUTRITION  
FACULTY OF FAMILY AND COMMUNITY SCIENCES  
MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA  
VADODARA 390 002 - INDIA



To,

Date: 19/10/12

Dr. Vipul Bhavsar,  
Mangalpur, Vadodara.

Sub: Permission of data survey in your hospital.

Dear Sir/ Madam,

This is to certify that Ms. Aditika Agarwal is a PhD. Scholar working under my supervision in the Dept. of Foods and Nutrition, Faculty of Family and Community Sciences, The M.S. University of Baroda. The topic of her research is "Intervention studies with vitamin B12 and omega-3 fatty acids for assessing nutrition and cognition levels in elderly with Mild Cognitive Impairment (MCI)". The study has been approved by the Departmental Ethical Committee No. FCSc/ FND/ME/101.

She would like to carry out her data survey followed by intervention by giving flaxseed supplementation on the elderly aged 60 -80 years. Kindly give her the permission for data collection in the OPD of your hospital.

Thanking You,

Yours Sincerely,

*Komal*

Dr. Komal Chauhan  
Associate Professor,  
Dept. of Foods and Nutrition.

*Chauhan*  
Prof. & Head  
Dept. of Foods & Nutrition

*Accepted*  
*[Signature]*  
24/10/12

Dr. VIPUL BHAVSAR      Dr. SHIKHA BHAVSAR  
Reg. No-G-8557 (M.D.)      Reg. No-G-8564 (M.D.)  
RUSHABH CLINIC & NURSING HOME  
205, Prime Canal, No. Sitabang Ground,  
Mangalpur, Vadodra. Pin: 0265-2656218

DEPARTMENT OF FOODS AND NUTRITION  
FACULTY OF FAMILY AND COMMUNITY SCIENCES  
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA  
VADODARA 390 002 - INDIA



Phone : 0265-2795526  
Tele. : 0265-2795522 [Ext.33]  
Grams : "HOMSCIENCE"  
No. F. C. Sc./ FND /

Date: 13/10/11

To,  
Dr. Kiran Shinglot,  
Officiating M.O.,  
University Health Centre,  
Vadodara.

Sub: Permission regarding data-survey in your hospital.

Dear Sir,

This is to certify that Ms. Aditika Agarwal is a Ph.D. Scholar working under the guidance of Dr. Komal Chauhan, from the Dept. of Foods and Nutrition, Faculty of Family and Community Sciences, The M.S. University of Baroda, Vadodara. She is carrying out the research work on the title, "Intervention studies with vitamin B12 and omega - 3 fatty acids and nutrition and cognition level in elderly with Mild Cognitive Impairment (MCI)".

She intends to survey in your reputed hospital. Kindly allow her to proceed further in her data collection through the O.P.D.

Thanking You.

Yours Sincerely,

*Pallavi Mehta*  
Prof. Pallavi Mehta  
Prof. & Head  
Dept. of Foods & Nutrition  
Prof. & Head  
Dept. of Foods & Nutrition

*She is permitted  
to conduct the  
data-survey in  
health centre  
population as per  
her study design.*

*K. N. Shinglot*  
13/10/11  
**Dr. K. N. Shinglot**  
M.B., B.S., D.C.H.  
MEDICAL OFFICER  
THE M.S. UNIVERSITY OF BARODA



DEPARTMENT OF FOODS AND NUTRITION  
FACULTY OF FAMILY AND COMMUNITY SCIENCES  
THE MAHARAJA SAYAJIRAO UNIVERSITY OF BARODA  
VADODARA 390 002 - INDIA



Phone : 0265-2795526  
Tele. : 0265-2795522 [Ext.33]  
Grams : "HOMSCIENCE"  
No. F. C. Sc./ FND /

Date: 7/9/11

To,  
Dr. Bhavin Upadhyay.  
Dandia Bazaar  
Kharivav Rd, Vadodra.

Sub: Permission regarding data-survey in your hospital.

Dear Sir,

This is to certify that Ms. Aditika Agarwal is a Ph.D. Scholar working under the guidance of Dr. Komal Chauhan, from the Dept. of Foods and Nutrition, Faculty of Family and Community Sciences, The M.S. University of Baroda, Vadodara. She is carrying out the research work on the title, "Intervention studies with vitamin B12 and omega - 3 fatty acids and nutrition and cognition level in elderly with Mild Cognitive Impairment (MCI)".

She intends to survey in your reputed hospital. Kindly allow her to proceed further in her data collection through the O.P.D.

Thanking You,

Yours Sincerely,

Pallavi M. Mehta

Prof. Pallavi Mehta  
Prof. & Head  
Dept. of Foods & Nutrition  
Prof. & Head  
Dept. of Foods & Nutrition

DR. BHAVIN UPADHYAYA  
M.D. (Neurology) D.M. (Neurology) (Bombay)  
Consultant Neurophysiologist  
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Vadodara - 01. Ph. (O) 0265 - 2434644