FORM A – Screening Part 1 CARRS Translation Trial

- ٠
- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)** Place cross [X] in the appropriate boxes. Write in fields clearly. ٠
- ٠
- See Form Completion Notes for definitions and explanations Store copies of available source documents (SD), where indicated, in patient's trial folder ٠

Complete by STUDY PHYSICIAN

Form - A - Data is saved in "patient.csv" and is in wide format

1.	Consent & Contact Information *ma	indatory fields
1.01	[]Y []N Signed informed consent for	or study participation obtained
1.02	Name [firstname] [varchar(50)] [lasttname] [varchar(50)]	First:* Middle: Last:*
1.03	Mailing Address [line1] [varchar(250)] [line2] [varchar(250)] [city] [varchar(100)] [pincode] [varchar(20)] [state] [varchar(100)]	Address 1:* Address 2: City:* Pin code:* State:*
1.04	Mobile* [mobile] [varchar(10)]	91
1.05	Phone 2 [phone] [varchar(20)]	
1.07	Email ID <mark>[email] [varchar(100)]</mark>	
1.08	Contact person	Relation: *Name: *Mobile: 91

General Inclusion Criteria 2.

	2.01	// / Date of Birth (dd/MMM/yyyy)		
		[date_of_birth] [date]		
		Age → If <35 years, patient is ineligible. Stop here a [age] [int(11)]	& <u>go to 4.01</u> in this form.	Commented [CR1]: No values are stored in this variable
	2.02	[]male []female		
		[sex] [varchar(10)] [Male M, Female F]		
	2.03	[]Y []N Diagnosis of Type 2 Diabetes (2006 WHO)		
SD	2.04	[]Y []N HbA1c≥8.0% irrespective of medications	f available, last HbA1c: %	
		E E E E E E E E E E E E E E E E E E E	Date: / /	
SD	2.05	[]Y []N []unknown <u>At least 1</u> of the following:		
SD		[] LDL ≥ 130 mg/dL	f available, last LDL: mg/dL	
CVDD	C Tranal	letion Trial: Form A Sereening Bart 1	ng 1 of 2	

ARRS Translation Trial; Form A – Screening Part 1 v1.3-21MAY2011

pg 1 of 2

				irrespective of medications	Date:/ / /
SD				[] Systolic BP ≥ 140 mmHg irrespective of medications	If available, last BP: / Date: / / / BP today: /
	2.06	[]Y []N	if in the inve	diabetes care in the same clinic fo estigator's assessment the patien the protocol.	r at least 3 months OR even earlier t is likely to follow-up regularly as

2.07 Review 2.03-2.06 above. If any boxes have been <u>marked 'N'</u> → Patient is ineligible. Stop here & go to 4.01 in this form. Otherwise, continue to next section.

3. General Exclusion Criteria

	Cross if	
	present	
3.01	[]	Known Type 1 Diabetes
3.02	[]	Diabetes secondary to chronic pancreatitis
3.03	[]	Pregnant OR trying to become pregnant OR of child-bearing potential and not actively
		practicing birth control (including natural methods)
3.04	[]	Documented cardiovascular event within the past 12 months
		[] Coronary Revascularization
		[] Myocardial Infarction
		[] Unstable angina
		[] Stroke
3.05	[]	Current symptomatic CHF, NYHA Class 3 or 4 CHF effort intolerance
3.06	[]	Non-diabetic kidney disease
3.07	[]	Pre-existing end-stage renal disease (dialysis or transplant)
3.08	[]	Active liver disease
3.09	[]	Malignancy or life-threatening disease with death probable in less than 4 years
3.10	[]	Current medication with known adverse interactions with glycemic treatments
		(e.g. long-term steroids, protease inhibitors)
3.11	[]	Plans to shift to out of the city in the next 4 years
3.12	[]	On an investigational drug for clinical trial in the last 3 months
3.13	[]	Currently participating in a clinical trial
3.14	[]	A member of the participant's household is currently enrolled in CARRS Trial
3.15	[]	No fixed address or contact details
3.16	[]	Any other condition or circumstance that, by the study physician's judgment, would interfere
		with participant's diabetic status OR adherence, such as:
		[] Other endocrinopathy (adrenal, pituitary),
		[] History of organ transplant,
		[] On tuberculosis treatment,
		[] Significant psychiatric illness/ cognitive impairment,
		[] Alcohol or substance abuse
		[] Other:

3.17 Review 3.01-3.16 above. If any boxes are crossed, patient is ineligible. Continue to next section.

4.	Eligibility
4.01	[]Y []N Patient ELIGIBLE for the trial so far
	If YES, continue to 4.02. If NO, go to Section 5.
4.02	/ / / Date of laboratory visit (within 2 weeks from today)
	(1)serum creatinine (2)sodium & potassium (3)ALT (4)venous FBG (5)HbA1c

(6)lipid profile (Total Chol, HDL, LDL-indir, Trig) (7)urine albumin:creatinine ratio

CARRS Translation Trial; Form A – Screening Part 1 v1.3-21MAY2011

pg 2 of 2

Provide appointment slip for laboratory investigations to patient. Instruct patient to arrive FASTING overnight/minimum 8 hours.

4.03	//	Date of next study visit (same as lab visit above, OR within 4 weeks of today)

5.	Signature of Study Physician	
5.01	Name:	S

Signature: _____

- 5.02 Date Signed: ___ / ___ / ___ / ___ __ / ____
- 5.03 Complete **Participant Log** for this patient

FORM B – Screening Part 2 CARRS Translation Trial

Complete by STUDY PHYSICIAN

PlacSee	ates dd/MMM/yyyy (e.g. 31/DEC/2010) the cross [X] in the appropriate boxes. Write in <i>Form Completion Notes</i> , for definitions and the copies of available source documents (SD	explanations), where indicated, in patient's tria		
	Screening ID: S		Data en	try by: <mark>try_by] [varchar(50)]</mark>
	Participa			try_byj [varchar(50)]
	Date of Visit (dd/MMM/yyyy): / /		DATE e	
				//
	[date_of_visit] [date]		[dateent	er] [date]
1.	Intake (SD for 1.02-1.04)	L		
1.01	[]Y []N SAE since last visit (MC	DP for definition)	→	SAEs:
	→ If YES, complete Form			-Death
	[adverse_event] [varchar(6)]			-Transient Ischemic Attack -Stroke (intracerebral/ischemic)
1.02	Heart rate	_ (beats/min)		-Stable Angina -ACS: Unstable Angina OR MI
	[heart_rate] [int(3)]			-Arrhythmia
1.03	Blood pressure 2 nd reading	/ (mmHg)		-Gastrointestinal bleeding -Eye diseases-Diabetic Retinopathy
	[blood_pressure_h_1] [int(3)]	/ [blood_pressure_l_1] [int(3	3)]	-Major infection -Renal failure
1.04	Blood pressure 3 rd reading	_ / (mmHg)		-Revascularization /other surgical
1.05	[blood_pressure_h_2] <mark>[int(3)]</mark> BP AVERAGE (calculate)	/ <mark>[blood_pressure_l_2]</mark> [<mark>int(3</mark> / (mmHg) (review - be		procedures -Other major health condition requiring hospitalization
1.06	<mark>[blood_pressure_h_avg]</mark>	[blood_pressure_l_avg] [dou _ (cm)	uble]	
1.07	[waist_circumference] [double] Weight	_ (kg)		
1.08	[weight] [double] Height [height] [double]	_ (cm)		
1.09		(kg/m²) (review - below)		
2.	Investigations (SD for 2.01-2.11)	DATE:///		(dd/MMM/yyyy)
۷.	[investigations_date] [date]			
2.01	Creatinine			
2.01	[creatinine_mg] [double]	(mg/dL)		
2.02	Sodium	(mEq/L)		
	[sodium] [double]			
2.03	Potassium [potassium] [double]	(mEq/L)		
2.04	[botassidin] [double] HbA1c [hemoglobin_a1c] [double]	% (review - below)		
2.05	ALT	(units/L) (review - bel	low)	
	[alt] [double]		,	
2.06	Total Cholesterol	(mg/dL)		
2.00	[total_cholesterol] [double]			
2.07	HDL Cholesterol	(mg/dL)		
	[hdl_cholesterol] [double]	/ / II \/		
2.08	LDL Cholesterol (indirect)	(mg/dL) (review - belo	ow)	
	[Idl_cholesterol] [double]	,		
2.09	Triglycerides	(mg/dL)		
	[triglycerides] [double]			
2.10	Fasting blood glucose (venous)	(mg/dL)		
	[fasting_blood_glucose_mgdl] [double]			
2.11	Urine Albumin:Creatinine Ratio [s_albumin_mg] [double]	(mg/g)		

FORM B – Screening Part 2

CARRS Translation Trial

Complete by STUDY PHYSICIAN

2.12 GFR (calculate <u>www.nephron.com/cgi-bin/CGSI.cgi</u>) ___ ml/min/1.73m² (review - below) [gfr] [double]

3. Study Continuation / Selection Criteria [study_continuation] [No Data for this variable]

Participant is (check 1 or 2):

1[]	INELIGIBLE for the study due to the FOLLOWING (Review values above with following criteria):			
	[] Serious Adverse Event that falls under exclusion criteria			
	[] BMI \ge 45 kg/m ² (obtain from calculation)			
	[] BOTH LDL ≤ 130 mg/dI AND systolic BP < 140 mmHg			
	[] HbA1c < 8.0%			
	[] ALT >3 times upper limit of normal			
	[] GFR < 15 ml/min/1.73 m ² (obtain from calculation)			
	[] Participant is eligible but does not wish to continue			
	[] Other, specify:			
	Do not enroll patient. Stop here- complete Section 4 (Signature). Inform patient of ineligibility.			
2[]				
2[] 4.	Do not enroll patient. Stop here- complete Section 4 (Signature). Inform patient of ineligibility.			
	Do not enroll patient. Stop here- complete Section 4 (Signature). Inform patient of ineligibility. ELIGIBLE for the study and wishes to continue. Complete Section 4 & Continue to Form C.			
4.	Do not enroll patient. Stop here- complete Section 4 (Signature). Inform patient of ineligibility. ELIGIBLE for the study and wishes to continue. Complete Section 4 & Continue to Form C. Signature of Study Physician			

		ſ	Participant ID: [participant_id] [varchar(20)]
FORM	D – 3 monthly Visit_Intervention		Participant Initials:
CARRS [·] Care Coo	Translation Trial	Date of Visit (dd/MMM/yyy	y):/ / / / [dateofvisit] [date]
	s dd/MMM/yyyy (e.g. 31/DEC/2010)		
Place See F	cross [X] in the appropriate boxes. Write number i orm Completion Notes, for definitions and explana copies of available source documents (SD), where	ations	Data entry by: [data_entry_by] [varchar(100)] Initials DATE entered: // [date_entered] [date]
1.	Intake FORM D – Data saved in "patient_f	orm_d.csv" and is in long f	ormat
1.01	Reason for Visit: 1[] medication check	2[] Other, specify:	
1	[reason_of_visit] [Int(11)] [medication check 1, o	ther 2]	
	[reason_of_visit_other] [varchar(200)]		
1.02	Complaints/Update: [complaints] [varchar(500)]		
1.03	Number of severe hypoglycemic episodes sin (If present, complete Form X with investigate [severe_hg_count] [int(11)]		
1.04	Number of mild hypoglycemic episodes since	last visit	
	[mild_hg_count] [Int(11)]		
4.05		to Forme V with investigator	
<mark>1.05</mark>	Other SAE since last visit (If present, comple	te Form X with investigator) []Y []N
2.	Measures (SD for 2.02-2.04)		
2.01	Weight	(kg)]
	[weight] [double]	(),	
2.02	Heart rate	(beats/n	nin)
	[heart_rate] [Int(11)]		
2.03	Blood pressure 2 nd reading	/ (r	mmHg)
	[blood_pressure_h_1] [Int(11)]		
	[blood_pressure_I_1] [Int(11)] [blood_pressure_h_avg] [double]		
2.04	Blood pressure 3 rd reading	/ (r	nmHg)
	[blood_pressure_h_2] [Int(11)]		0,
	[blood_pressure_I_2] [Int(11)]		
	[blood_pressure_l_avg] [double]		
3.	Investigations (SD for all)		
Write in	other investigations/exams below. Retain recor	de of results as source doc	uments
3.01	HbA1c [hemoglobin_a1c] [double]	% Date:	// []N/A
	[hemoglobin_a1c_date] [date]		-
	[hba_not_applicable] [Int(11)] [-1]		
3.02	Fasting blood glucose (venous)	(mg/dL) Date:	// [] N/A
0.02	[fasting_blood_glucose] [double]		

CARRS Translation Trial; Form D – 3-monthly Visit_Intervention v1.2 17JUL2010

I

Page 1 of 3

	[fasting_blood_glucose_date] [date] [fbg_not_applicable] [Int(11)] [-1]			
3.03	Post-prandial blood glucose (venous) [post_prandial_blood_glu] [double] [post_prandial_blood_glu_date] [date] [ppbg_not_applicable] [Int(11)] [-1]	(mg/dL)	Date: / / / /	[] N/A
3.04	LDL [Idl] [double] [Idl_date] [date] [Idl_not_applicable] [Int(11)] [-1]	(mg/dL)	Date: / / /	[] N/A

Update Form G-Eye Exam results if not done at previous visit.

Indicate in Form C (Baseline_Randomization) or Form E (Follow-up 12 monthly_All).

4. Self-Care

The questions below ask you about your diabetes self-care activities during the past 7 days.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET	-									
4.01	On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?			1	2	3	4	5	6	7
	[selfcare_id=1] [Int(11)] [0 1 2 3 4 5 6 7]									
EXERC	ISE									
4.02	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)		0	1	2	3	4	5	6	7
	[selfcare_id=2] [Int(11)] [0 1 2 3 4 5 6 7]									
BLOOD	SUGAR TESTING									
4.03	Are you testing your blood sugar as recommended by your health care provider?		0[]No							
	[selfcare_id=3] [Int(11)] [No 0, Yes 1, N/A -1]		1 [] Yes				2 [] N/A			
FOOT	CARE									
4.04	On how many of the last SEVEN DAYS did you chec feet?	k your	0	1	2	3	4	5	6	7
	[selfcare_id=4] [Int(11)] [0 1 2 3 4 5 6 7]									
MEDIC	ATIONS									
4.05	On how many of the last SEVEN DAYS, did you take your recommended diabetes medication? (pills and/or insulin)		0	1	2	3	4	5	6	7
	[selfcare_id=5] [Int(11)] [0 1 2 3 4 5 6 7]									
TOBAC	со	r								
4.06	Smoke regularly? (most days of the week)	0[]Neve	er							
	[selfcare_id=6] [Int(11)] [Never 0, Quit 1, Yes 2] 1 [] Q			uit: / / (MMM/yyyy)						y)
	[if Quit 1] → [quit_smoking_year] [varchar(20)]	2[]Yes,	, # smoked per day:							

Formatted Table

CARRS Translation Trial; Form D - 3-monthly Visit_Intervention v1.2 17JUL2010

Page 2 of 3

	[if Yes 2]→ [smoke_per_day] [Int(11)]			 Commented [CR3]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day
4.07	Chew tobacco regularly? (most days of the week) [selfcare_id=7] [Int(11)] [Never 0, Quit 1, Yes 2] [if Quit 1]→ [quit_tobacco_year] [varchar(20)] [if Yes 2]→ [packet_per_day] [Int(11)]		/ (MMM/yyyy) # packets per day:	Commented [CR4]: If the response is [quit 1] specify the year &
ALCOH	łOL	1		response is [yes 2] specify no. packet per day
4.08	Drink alcohol regularly? (at least once a week for mo in past year) One drink: wine=100 ml, spirit=30 ml, beer= [selfcare_id=8] [Int(11)] [No 0, Yes 1] [if Yes 1]→ [drink_per_day] [Int(11)]		0 [] No 1 [] Yes, # drinks per day:	Commented [CR5]: If the response is [yes 1] specify no. drink
STRES				 per day
4.09	How often do you feel stress (from work, responsibilit [] daily [] few times a week [selfcare_id=9] [Int(11)] [daily 1, few times a week 2, few times	[]few		

5. Data Entry & Care Coordinator Signature

5.01 Name: ____

_ Signature: ___

5.03 DSS Instructions:

(1) Enter all visit information above into Form D eCRF. Print Form Z (Intervention Management Plan).

(2) Review patient medications. Update medication changes in writing on Form Z in medication section.

(3) Provide paper Form Z (with medication update) to study physician during consultation with participant.

(4) Attach completed Form Z to this Form D; Update patient with information.

(5) After patient leaves, update Form Z information in eCRF.

(6) Keep relevant source documents in participant's trial folder. Include copy of any visit note if available.

Form G - EYE EXAM FORM v1.2-1	7JUL2010		Participa	nt ID:
CARRS Translation Trial			-	
				Site No:
o be completed by qualified op	hthalmologist on	ly Inves	tigator:	
eferral to:		Appointment D	A <i>TE:</i> /_	/
EYE EXAM Date: [s_eye_exam_date] [da				
Right Eye, Visual acuity	Snellen Fracti	on: 6/	[] new or w	vorsened
	[s_eye_exam	right_eye]		ed or improved
	[int(11)]			am_newunch] [int(11)] ed 1, unchanged or improved 0]
Left Eye, Visual acuity	Snellen Fracti	on: 6/	[]new or w	
	[s_eye_exam			ed or improved
	[int(11)]		[eye_lft_exa	m_newunch] <mark>[int(11)]</mark>
			[new or worsen	ed 1, unchanged or improved 0]
Fundoscopy				
Macular Edema		1[] absent		[] new or worsened
[s_fundoscopy_macular_eden		2[] mild		[] unchanged or improved [muculared_new_unch] [int(11)]
[absent 1, present 2, mild 3, moderate	e 4, severe 5]	3[] moderate		[new or worsened 1, unchanged or impro
		4[] severe		
Diabetic Retinopathy		1[] no apparent	t	[] new or worsened

[] unchanged or improved

[s_fundoscopy_diabetic] [int(11)] [no apparent 1, mild non-proliferative 2, moderate non-	2[] mild r	on-proliferative	[] unchanged or improved		
proliferative 3, severe non-proliferative 4, proliferative 5]	3[] mode proliferativ		[diabetic_reti_new_unch] [int(11)] [new or worsened 1, unchanged or improved 0]		
	4[] sever	e non-proliferative			
	5[] proliferative				
Previous Laser Therapy evident	1[]Y	2[]N] new or worsened] unchanged or improved		

Other details:

Please attach a copy of the exam note/results.

[s_fundoscopy_diabetic] [int(11)]

Ophthalmologist Name: _

_____ Signature: __

To study staff- This Form G - Eye Exam must accompany all of the following:

Form C (Baseline_Randomization), Form E (12-monthly), and Form F (Close-out)

Page 1 of 1

			Participant ID: [participant_id] [
	I.i – Intermediate Visit_Intervention Translation Trial Date	of Visit (dd/MMM/yy	Participant Init	
Care Co			[dateofvisit] [dat	te]
 Place 	s dd/MMM/yyyy (e.g. 31/DEC/2010) cross [X] in the appropriate boxes. Write number in spac copies of available source documents (SD), where indica		Ider Data entry by: [data_entry_by] [Initials DATE entered: / /	
1.	Intake FORM D – Data saved in "patient_form_d	I.csv" and is in long f	[date_entered] [d	date]
1.01	Reason for Visit: 1[] medication check 2[] C [reason_of_visit] [Int(11)] [medication check 1, other 2] [reason_of_visit_other] [varchar(200)]	Dther, specify:		
1.02	Complaints/Update: [complaints] [varchar(500)]			
1.03	Number of severe hypoglycemic episodes since last (If present, complete Form X with investigator) [severe_hg_count] [Int(11)]	: visit		
1.04	Number of mild hypoglycemic episodes since last vi	sit		
1 05	[mild_hg_count] [Int(11)]	N 11 1 1 1 1 1		
<mark>1.05</mark>	Other SAE since last visit (If present, complete For	m X with investigator	[]Y	[]N
2.	Measures (SD for 2.02-2.04)			
2.01	Weight [weight] [double]	(kg)		
2.02	Heart rate [heart_rate] [Int(11)]	(beats/r	nin)	
2.03	Blood pressure 2 nd reading [blood_pressure_h_1] [Int(11)] [blood_pressure_l_1] [Int(11)] [blood_pressure_h_avg] [double]	/(r	nmHg)	
2.04	Blood pressure 3 rd reading [blood_pressure_h_2] [Int(11)] [blood_pressure_I_2] [Int(11)] [blood_pressure_I_avg] [double]	/ (r	nmHg)	
3.	Investigations (SD for all)			
Write in	other investigations/exams below. Retain records of r	esults as source doc	uments.	
3.01	HbA1c [hemoglobin_a1c] [double] [hemoglobin_a1c_date] [date] [hba_not_applicable] [Int(11)] [-1]	_% Date: _ 	///	[] N/A
3.02	Fasting blood glucose (venous)	_ (mg/dL) Date: 	//	[] N/A

CARRS Translation Trial; FORM I.i – Intermediate Visit_Intervention v 1.2 17JUL2010

Page 1 of 3

	[fbg_not_applicable] [Int(11)] [-1]			
3.03	Post-prandial blood glucose (venous) [post_prandial_blood_glu] [double] [post_prandial_blood_glu_date] [date] [ppbg_not_applicable] [Int(11)] [-1]	(mg/dL)	Date:////	[] N/A
3.04	LDL [Idl] [double] [Idl_date] [date] [Idl_not_applicable] [Int(11)] [-1]	(mg/dL)	Date: / / /	[] N/A

Update Form G-Eye Exam results if not done at previous visit.

Indicate in Form C (Baseline_Randomization) or Form E (Follow-up 12 monthly_All). 4. Self-Care

The questions below ask you about your diabetes self-care activities during the past 7 days.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET										
4.01	On average, over the past month, how many DAYS PEI WEEK have you followed your diet plan?	0	1	2	3	4	5	6	7	
	[selfcare_id=1] [Int(11)] [0 1 2 3 4 5 6 7]									
EXERCI	ISE		-							
4.02	On how many of the last SEVEN DAYS did you particip at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)	0	1	2	3	4	5	6	7	
	[selfcare_id=2] [Int(11)] [0 1 2 3 4 5 6 7]			_	_	_	_	_	_	
OOD SL	JGAR TESTING									
4.03	Are you testing your blood sugar as recommended by your health care provider?				_		0.1	1.51/4		
	[selfcare_id=3] [Int(11)] [No 0, Yes 1, N/A -1]		ЧĻ	Jre	s		2 [] IN/F	4	
FOOT CARE										
4.04	On how many of the last SEVEN DAYS did you check y feet?	/our	0	1	2	3	4	5	6	7
	[selfcare_id=4] [Int(11)] [0 1 2 3 4 5 6 7]									
MEDICATIONS										
4.05	On how many of the last SEVEN DAYS, did you take yo recommended diabetes medication? (pills and/or insulin	0	1	2	3	4	5	6	7	
	[selfcare_id=5] [Int(11)] [0 1 2 3 4 5 6 7]									
ТОВАССО										
4.06	[selfcare_id=6] [Int(11)] [Never 0, Quit 1, Yes 2] [if Quit 1]→ [quit smoking year] [varchar(20)]	[]Neve []Quit: []Yes,						MMN	1/уууу	/)

CARRS Translation Trial; FORM I.i – Intermediate Visit_Intervention v 1.2 17JUL2010

Page 2 of 3

Commented [r3]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

4.07	It Quit $1 \rightarrow 1$ duit tobacco year 1 varchar(20)	it / (MMM/yyyy) s, # packets per day:	Commented [r4] : If the response is [quit 1] specify the year &
ALCOH	IOL		response is [yes 2] specify no. packet per day
4.08	Drink alcohol regularly? (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [selfcare_id=8] [Int(11)] [if Yes 1] → [drink_per_day] [Int(11)]	Commented [r5]: If the response is [yes 1] specify no. drink	
STRES	S		per day
4.09	How often do you feel stress (from work, responsibilities, etc)? [] daily [] few times a week [] few times a week 2, few times a month [selfcare_id=9] [Int(11)] [daily 1, few times a week 2, few times a month	ew times a month [] never	

5.01 Name: _____

_____Signature: ____

5.03 DSS Instructions:

(1) Enter all visit information above into Form D eCRF. Print Form Z (Intervention Management Plan).

(2) Review patient medications. Update medication changes in writing on Form Z in medication section.

- (3) Provide paper Form Z (with medication update) to study physician during consultation with participant.
- (4) Attach completed Form Z to this Form D; Update patient with information.
- (5) After patient leaves, update Form Z information in eCRF.
- (6) Keep relevant source documents in participant's trial folder. Include copy of any visit note if available.

CARRS Translation Trial Visit Date: [dd/MMM/yyyy] Form Z- Intervention Management Plan v1.2-17JUL2010 Form Z - Data saved in dataset as "patient_formz.csv" and is in long format

[First Name, Last Name] [Age] [M/F] DOB[dd/MMM/yyyy] [Conditions – from Form C, updates Form E] Allergies: [none, listing]

	Wt	BMI		Self-Care	Status
01/05/1	0			Adherence Medication	
02/02/1	0			Adherence SMBG	
01/12/0	9			Following Exercise	
				Following Diet	
				Smoking	
Since la	ast visit:			Chew Tobacco	
Sever	e hypos		(#)	Alcohol	
Mi	Mild hypos (#)		Stress		

Commented [CR1]: Wt, BMI, Waist, HbA!c, FBG, PPBG, BP, TC, LDL, HDL, TG all fields come from in any of the Forms D/I, E

				_			
Date	HbA1c	FBG	PPBG	Prompt		Accept	If NO, reason
1				(from algori	ithm	[]Y	
				according to Hb	A1c and		
				fasting blood g	glucose	[]N	
L	1			values – open s	-	diabetes mplan selecte	ed] [diabetes no mplan]
				accommodate l	•	[varchar(5)] [Yes 1, No 2]	[varchar(500)]
				prompt			
				[STATUS			
Dat	e E	BP		-	-		
	130	0/80		[RECOMMEND			
				[diabetes_m			
				[varchar(50	<u>[(OC</u>		
		Bro	mnt			Accept	If NO, reason
(6	Prompt					•	in NO, reason
	(from algorithm according to blood pressure values – open space to accommodate length of					[]Y	
values -	- open sp			ouate length of		r	
	prompt)					[]N	
	[STATUS]				-	bp_mplan_selected]	[bp_no_mplan]
	[RECOMMENDATION]				[varchar(5)] [Yes 1, No 2]	[varchar(500)]
	[bp_mplan] [varchar(500)]						
Date	TC LC	DL HD	L TG				
	<u> </u>	Pro	mpt			Accept	If NO, reason
(from alg	(from algorithm according to LDL values – open space					[]Y	,
	to accommodate length of prompt)						
		[STA	•	,		[]N	
	[RE	-	ENDATIO	N]	ri ri	dl mplan selected]	[IdI no mplan]
[ldl_m	nplan] [v				-	varchar(5)] [Yes 1, No 2]	[varchar(500)]
[]	-le , er		10/1		L		

PHYSICIAN NAME:

SIGNATURE: _____ [dd/MMM/yyyy]

Form Z- Interv	vention Management	t Plan v1.2-17JUL2010	CARRS Translati	CARRS Translation Trial Visit Date: [dd/MMM/yyy		
	RE	SULT	LAST test	NEXT test		
ECG			(date)	(date)		
EYE			(date)	(date)		
FOOT			(date)	(date)		
KIDNEY	Creatinine	A:C Ratio		(date)		
			(date)			
			(date)	1		

[First Name, Last Name] [Age] [M/F] DOB[dd/MMM/yyyy] Allergies: [none, listing]

[Conditions – from Form C, updates Form E]

Current medications listed below. Make changes in right column. Add NEW medications to bottom of list. _ (Y/N) TV = Telephonic contact with clinic/doctor to change meds since last visit (update below) _

[doctor_change_med] [int(11)] [Yes 1, No 2] (Y/N) Other outside changes to meds (update below)

<pre>[other_change_</pre>	med] [int(11]	[Yes 1, No 2]

Brand Name (if available)	Generic Name (constituents)	Single Dose (constituents)	Frequency	Total daily dose	√to keep same OR write changes in dose

PHYSICIAN NAME: ______ SIGNATURE: _____ [dd/MMM/yyyy]

Form Z- Intervention Management Plan v1.2-17JUL2010 CARRS Translation Trial Visit Date: [dd/MMM/yyyy] [] Anti-platelet included [] ACE-inhibitor or ARB included

[anti_platelet] [int(11)] [1]

[arb_included] [int(11)] [1]

					NE7	(T VISIT in	mo//
	REFERRAL	Today	Other DATE				[next_visit] [date]
[]	Dietician/Educator [dietician_educator] [int(11)] [1]		/ / [dietician_educator_date] [date]		Tes	ts prior to	o next visit:
[]	ECG <mark>[ecg]</mark> [int(11)] [1]		/ / [ecg_date] [date]		[]	HbA1c <mark>[hba1c]</mark>	[int(11)] [1]
[]	Ophthalmology [<mark>ophthalmogy]</mark> [int(11)] [1]		/ / // [ophthalmogy_date] [date]		[]		blood glucose (venous) glu] <mark>[int(11)]</mark> [1]
[]	Podiatry [podiatry] [int(11)] [1]		/ / [podiatry_date] [date]		[]		ndial blood glucose
[]				-	[]		m & Sodium (serum) Im sodium [int(11)] [1]
[]					[]	Creatinin	ne (serum) ne [int(11)] [1]
[]	LAB today, tests: [lab_today] [int(11)]	[1]	· ·		[]		croalbuminuria icroal] <mark>[int(11)]</mark> [1]
	[lab_test] [text]				[]		nel <mark>nel]</mark> [int(11)] [1]
					[]	ALT [alt] [int	(11)] [1]
					[]	Other: [other] [i	int(11)] [1]

Commented [CR2]: If response is "other" there should be other specify variable not found in database

PHYSICIAN NAME: ______ SIGNATURE: _____ [dd/MMM/yyyy]

 Place See I Store in pat 	tes dd/MMM/yyyy (e.g. 31/DEC/20 e cross [X] in the appropriate boxes. Form Completion Notes, for definitio copies of available source docume tient's trial folder	Write in fields c ins and explanat nts (SD), where	learly. [d tions In indicated, D	lata_er iitials _ ATE e	try by: htry_by] [varchar(100)] ntered: / / htered] [date]		
CARRS	I C – Baseline Randomizatior S Translation Trial story – Data saved in "patient_f	Dat		Pa [pa	eening ID: S rticipant Initials: articipant_id] [varchar(20)] / / / [date_of_visit] [date]		
		Year of Diagnosis					
1.01	Type 2 Diabetes [h_type2_diabetes_year] [varchar(6)]		1[] Unknown [h_is_type2_diabetes [int] [Unknown 1]]			Commented [CR1]: If the response is [Unknown] data is saved as '1'
1.02	Hypertension [h_hypertension_year] [varchar(6)]		1[] Unknown [h_is_hypertension] [int] [Unknown 1, Not ap	plicable	2[] Not applicable		Commented [CR2]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'
1.03	Hyperlipidemia [h_hyperlipidemia_year] [varchar(6)]		1[] Unknown [h_is_hyperlipidemia] [int] [Unknown 1, Not ap		2[] Not applicable		Commented [CR3]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'
1.04	How first diagnosed with diabet [h_first_diagnosed_with_diabete [Testing after symptoms emerged 1, At routine check-up, no symptoms 2, Active screening 3, Diagnosed during pregnancy 4, Other 5]		/mptoms emerged a, polyphagia, weight loss, low energy, vision problems, giddiness, aches/pains) k-up, no symptoms (urine test, lg (testing by ing pregnancy				
		Diabetes?		Kidı	ney failure?		
	Number of children with [h_no_children_with_diabetes] [int(11)] [h_no_children_with_kidney_fail ure] [int(11)]	-	nown, N/A <mark>I_with_diabetes_fail]</mark>		[] Unknown, N/A [is_chid_with_kidney_fail] [int] [-1]		Commented [CR5]: If the response is [Unknown, N/A] data is saved as '-1' Commented [CR4]: If the response is [Unknown, N/A] data is saved as '-1'
1.06	Number of brothers/sisters with [h_no_brother_sister_with_diabe		nown, N/A		[] Unknown, N/A	K	Commented [CR7]: If the response is [Unknown, N/A] data is saved as '-1'

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

[is_brosis_with_diabetes] [int] [-1]

_

_

[Int(11)] [h_no_brother_sister_with_kidne y_failure] [int(11)]

Page 1 of 28

[is_brosis_with_kidney_fail [int] [-1]

Commented [CR6]: If the response is [Unknown, N/A] data is saved as '-1'

1.07	Number of parents with [h_no_parents_with_diabetes] [int(11)] [h_no_parents_with_kidney_failu re] [int(11)]	 [] Unknown [is_parents_with_diabetes] [int] [-1]	 [].Unknown [is_parents_with_kidney_fa il] [int] [-1]	Commented [CR8]: If the response is [Unknown] data is saved as '-1' Commented [CR9]: If the response is [Unknown] data is saved as '-1'
1.08	Number of grandparents with [h_no_grandparents_with_diabet es] [int(11)] [h_no_grandparents_with_kidne y_failure] [int(11)]	 [] Unknown [is_granparent_with_diabetes] [int] [-1]	 [] Unknown [is_granparent_with_kidne y_fail] [int] [-1]	Commented [CR10]: If the response is [Unknown] data is saved as '-1' Commented [CR11]: If the response is [Unknown] data is saved as '-1'

1.09	Is there a history of <u>HEART DISEASE or HEART ATTACK</u> in a brother, sister, or parent? <i>If YES, was it at an early age?</i> (Early age = Before Age 55 for father/brother; 65 for mother/sister) [h heart attack brother sister parents] [int(11)]	1[] Yes, at an EARLY AGE 2[] Yes, age unknown 3[] No 4[] Unknown
	[Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]	
1.10	Is there a history of <u>STROKE</u> in a brother, sister, or parent? If YES, was it at an early age? (Early age = Before Age 55 for father/brother; 65 for mother/sister) [h_stroke_brother_sister_parents] [int(11)] [Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]	1[] Yes, at an EARLY AGE 2[] Yes, age unknown 3[] No 4[] Unknown

	Cardiovascular	no/ unsure	yes		
1.11	ACS: Myocardial Infarction or Unstable Angina [h_cardiovascular_acs] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, list year(s): [h_cardiovascular_acs_year] [varchar(20)]	Commented [CR12]: If the response is [yes 1] for Q.no.1.11 to 1.16 - specify the year
1.12	Angioplasty (PCI) /Open-heart surgery (CABG) [h_cardiovascular_pci_cabg] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, list year(s): [h_cardiovascular_pci_cabg_year] [varchar(20)]	
1.13	Chronic Stable Angina [h_cardiovascular_chronic_sa] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, since (year): [h_cardiovascular_chronic_sa_year] [varchar(20)]	
1.14	Stroke (Ischemic or Hemorrhagic) or TIA [h_cardiovascular_stroke_tia] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, list year(s): [h_cardiovascular_stroke_tia_year] [varchar(20)]	
1.15	Arrhythmia (requiring medical intervention) [h_cardiovascular_arrtythmia] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, since (year): [h_cardiovascular_arrtythmia_year] [varchar(20)]	
1.16	Heart Failure	[]	[]	If yes, since (year):	
				B	

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 2 of 28

	[h_cardiovascular_heart_attack] [int(11)] [Yes 1, no/unsure 2,]		ardiova char(20	ascular_heart_attack_year]	
	Peripheral Vascular/Neuropathy	no/ unsure	yes		
1.17	PVD (Intermittent claudication/ rest pain in legs) [h_peripheral_vascular_pvd] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, since (year): [h_peripheral_vascular_pvd_year] [varchar(20)]	Commented [CR13]: If the response is [yes 1] for Q.no.1.17, 1.18 - specify the year & for Q.no.1.19 response is [yes 1] – specify number of times
1.18	Peripheral revascularization (angioplasty/ surgery) [h_peripheral_surgery] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	lf yes, list year(s): [h_peripheral_surgery_year] [varchar(20)]	
1.19	Chronic leg/foot ulcer (6 weeks or more) [h_peripheral_foot_ulcer] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, number of times: [h_peripheral_foot_ulcer_year] [varchar(20)]	
	Eyes	T T		· ·	
1.20	Blindness in either eye thought to be due to diabetes [h_eyes_blindbess] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, []R []L []both [h_eyes_is_blindbess] [varchar(20)] [R right, L left, B both]	Commented [CR14]: If the response is [yes 1] for Q.no.1.20 to 1.22 - specify the direction [right, left or both
1.21	Cataract [h_eyes_cataract] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, []R []L []both [h_eyes_is_cataract] [varchar(20)] [R right, L left, B both]	
1.22	Cataract Surgery [h_eyes_cataract_surgery] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, []R []L []both [h_eyes_is_cataract_surgery] [varchar(20)] [R right, L left, B both]	
1.23	Glaucoma [h_eyes_glaucoma] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.24					
1.2	[h_eyes_macular_edema] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.25	Diabetic Retinopathy [h_eyes_diabetic_retinopathy] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.26	Laser photocoagulation therapy [h_eyes_laser_therapy] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, number of <mark>times</mark> :	Commented [CR15]: We can ignore this because Variable not found in both front-end & back-end
1.27	Other therapy [h_eyes_other_therapy] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
	OTHER			·	
1.28	Neuropathy – hands/feet [h_other_neuropathy_hands_feet] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.29	Neuropathy – sexual (erectile dysfunction) [h_other_neuropathy_sexual] [int(11)] [Yes 1, no/unsure 2.]	[]	[]		
1.30	Nephropathy (protein in urine)	[]	[]		

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 3 of 28

	[h_other_neuropathy_urine] [int(11)] [Yes 1, no/unsure 2,]				
1.31	Chronic urinary tract infection (2+ in 6 months) [h_other_chronic_urinary] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.32	Past tuberculosis [h_other_past_tuberculosis] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.33	Asthma [h_other_asthma] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.34	COPD (Chronic Bronchitis, Emphysema) [h_other_copd] [int(11)] [Yes 1, no/unsure 2.]	[]	[]		
1.35	Liver disease [h_other_liver_disease] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.36	Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.37	Hip Fracture/Replacement [h_other_hip_facture] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.38	Depression [h_other_depression] [int(11)] [yes 1, no/unsure 2,]	[]	[]		
1.39	Major hypoglycemia episodes (hospitalization or emergency room visit) [h_other_major_hypoglycemia] [int(11)] [Yes 1, no/unsure 2.]	[]	[]	If yes, number of <mark>times</mark> : [h_other_is_major_hypoglycemia] [int(11)]	Commented [CR16]: If the response is [yes 1] for Q.no.1.39 & 1.40 – specify number of times
1.40	Other hospitalization for diabetes [h_other_hospitalization] [int(11)] [Yes 1, no/unsure 2]	[]	[]	If yes, number of times: [h_other_is_hospitalization] [int(11)]	
1.41	Other conditions (current or past) which have require [h_other_conditions] [varchar(200)]	ed medi	cations	or surgical intervention:	

2. ECG & Eye Exam

May use results from past 1 month. Retain copies of ECG and eye exam results as source documents.

ECG: May use results from past 1 month. Otherwise, complete test today.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 4 of 28

2.01	ECG Date:// [s_ecg	_date] [date]	
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] [Yes 1, No 2]	1[]Y	2[]N
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] [Yes 1, No 2]	1[]Y	2[]N
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] [Yes 1, No 2]	1[]Y	2[]N
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] [Yes 1, No 2]	1[] Y	2[]N

Commented [CR17]: ECG date should be within one month of Form B Date of visit

EYE EXAM: May use results from past 1 month.

[] Attach Form G-Eye Exam to end of this Form C – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 5 of 28

		Right Foot		Left Foot		
2.04	A manufaction					-
3.01	Amputation [fe_amputation_right_foot] [int(11)] [fe_amputation_left_foot] [int(11)] [IN/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5, below knee 6, above knee 7]	[] N/A [] toe [] ray (metatarsal) [] forefoot [] foot [] below knee [] above knee		[] N/A [] toe [] ray (metat [] forefoot [] foot [] below kne [] above kne	e	
3.02	Appearance [fe_appearance_right_foot_normal] [int(11)] [normal 1, abnormal 2] [fe_appearance_left_foot_normal] [int(11)] [normal 1, abnormal 2] [fe_appearance_right_foot_deformities] [int(11)] [1] [fe_appearance_right_foot_dystrophic] [int(11)] [2] [fe_appearance_right_foot_callus] [int(11)] [3] [fe_appearance_right_foot_unceration] [int(11)] [4] [fe_appearance_right_foot_infection] [int(11)] [5] [fe_appearance_right_foot_discoloration] [int(11)] [6] [fe_appearance_right_foot_other] [int(11)] [7] [fe_appearance_right_foot_other_details] [varchar(200)] [other specify]	1[] normal 2[] abnormal, che that apply: 1[] deformities 2[] dystrophic na skin/fissure 3[] callus 4[] ulceration 5[] infection 6[] discoloration 7[] other:	ils; dry	1[] normal 2[] abnorma that apply: 1[] deforn 2[] dystro skin/fissure 3[] callus 4[] ulcera 5[] infecti 6[] discol 7[]other:	nities phic nails; dry tion ion	Commented [CR18]: If the response is [abnormal 2] specify below mentioned options 1 to 7 (check all that apply) for right foot & left foot [fe_appearance_left_foot_deformities] [int(11)] [1] [fe_appearance_left_foot_dystrophic] [int(11)] [2] [fe_appearance_left_foot_callus] [int(11)] [3] [fe_appearance_left_foot_unceration] [int(11)] [4] [fe_appearance_left_foot_unceration] [int(11)] [5] [fe_appearance_left_foot_therolocration] [int(11)] [6] [fe_appearance_left_foot_therol_details] [varchar(200)] [other specify]
3.03	Posterior tibial pulse [fe_posterior_right_foot] [int(11)] [Yes 1, No 2] [fe_posterior_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[] N	
3.04	Doraslis pedis pulse [fe_doraslis_right_foot] [int(11)] [Yes 1, No 2] [fe_doraslis_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[]N	
3.05	Pre-tibial EDEMA today [fe_pre_tibial_edema_right_foot] [int(11)] [fe_pre_tibial_edema_left_foot] [int(11)] [None 0, up to ankle 1,between ankle & mid-calf 2, between mid-calf & knee 3]	[] none [] up to ankle [] between ankle & mid- calf [] between mid-calf & knee		[] none [] up to ank [] between calf [] between knee	ankle & mid-	
3.06	Ankle Reflex [fe_ankle_relax_right_foot] [int(11)] [Yes 1, No 2] [fe_ankle_relax_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[]N	
3.07	Knee Reflex [fe_knee_reflax_right_foot] [int(11)] [Yes 1, No 2] [fe_knee_reflax_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[]N	
3.08	Vibration, tuning fork (perception at great toe) [fe_vibration_right_foot] [int(11)] [fe_vibration_left_foot] [int(11)] [present (>10 sec) 1, reduced (<10 sec) 2, absent 3]	[] present (≥10 se [] reduced (<10 se [] absent		[] present (a [] reduced ([] absent	,	
0400	S Translation Trial: Form C – Baseline Randomization			Page 6	of 00	

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

3.09	10g Monofilament (number applications detected) [fe_monofilament_right_foot] [int(11)] [fe_monofilament_left_foot] [int(11)] [present (≥8) 1, reduced (1-7) 2, absent 3]	[] present (≥8) [] reduced (1-7) [] absent	[] present (≥8) [] reduced (1-7) [] absent	
3.10	Based on above the participant has:			
	Deformities	1[] Yes	2[] No	
	[fe_participant_has] [varchar(20)]			Commented
	[Yes 1, No -1]			responses and & re naming th
	Foot ulceration/infection [Yes 2, No -2]	1[] Yes	2[] No	
	PVD [Yes 3, No -3]	1[] Yes	2[] No	
	Neuropathy [Yes 4, No -4]	1[] Yes	2[] No	

Commented [CR19]: For Q.no.3.10 to 3.14 has multiple responses and data stored in this column as string so we are splitting & re naming the categories as [1,-1, 2,-2, 3,-3, 4,-4]

4. Heart Failure Exam

	Have you experienced any of the following th	owing since yo		
4.01	swelling of your feet, ankles or legs [hf_swelling_feet] [int(11)] [Yes 1, No 2, NA 3] [if Yes 1] →	1[] Yes → 2[] No	1[] new or worsened 2[] unchanged or improved [hf_is_swelling_feet_new] [new or worsened 1, unchanged or improved 0]	Commented [CR20]: If the response is [yes 1] for Q.no.4.01 to 4.03 – specify '1' or '0' [new or worsened 1, unchanged or improved 0]
4.02	shortness of breath while lying, sitting, or with minimal exertion [hf_shortness_of_breath] [int(11)] [Yes 1, No 2, N/A 3] [if Yes 1] →	1[]Yes → 2[]No	1[] new or worsened 2[] unchanged or improved [hf_is_shortness_of_breath_new] [new or worsened 1, unchanged or improved 0]	
4.03	need to pass urine two or more times per night [hf_pass_urine] [int(11)] [Yes 1, No 2, N/A 3] [if Yes 1] →	1[]Yes → 2[]No] new or worsened] unchanged or improved [hf_is_pass_urine_new] [new or worsened 1, unchanged or improved 0] 	

If any 4.01-4.03 is YES, complete below.								
Chest Auscultation								
4.04	Lungs [hf_chest_ausculation_lungs] [int(11)] [no rales 1, basilar rales only 2, more than basilar 3]	1[] no rales 2[] basilar rales only 3[] more than basilar						
4.05	Heart [hf_chest_ausculation_heart] [int(11)] [normal 1, abnormal 3rd heart sound present 2]	1[] normal 2[] abnormal, 3 rd heart sound present						
4.06	Heart Failure evident [hf_chest_ausculation_heart_failure] [int(11)] [Yes 1, No 2]	1[] Yes, grade: 2[] No [heart_failure_grade] [varchar(45)]						

Commented [CR21]: If the response is [yes 1] for Q.no.4.06 – specify grade

5. Neurological Exam

CARRS Translation Trial; Form C - Baseline_Randomization v1.4-3DEC2010

Page 7 of 28

	Here and the first state of the	- 11					
	Have you experienced any of the fo			[
	Muscle weakness		[] <mark>Yes_→</mark>	1[] new o			
5.01	[ne_muscles_weakness] [int(11)] [Yes 1, No 2, N/A 3] [if Yes 1] \rightarrow	2	[]No 2[]unchang			a of improved <mark>s_weakness_r</mark>	ewl [int(11)]
				-		1, unchanged or	
	Difficulty in speech	1	[]Yes →	1[] new o	r wo	orsened	
5.02	[ne_difficulty_in_speech] [int(11)]	2	[] No	2[] uncha	inge	d or improved	
	[Yes 1, No 2, N/A 3] [if Yes 1] →			-		n_speech_new	
	Loss of consciousness	1	[]Yes		eneu	1, unchanged or	improved oj
5.03	[ne_loss_consciousness] [int(11)]] No				
	[Yes 1, No 2, N/A 3]						
If any	5.01-5.03 is YES, complete below.						
	Muscles		Right			Left	
	ARMS-Tone						
5.04	[ne_arms_tone_right] [int(11)]		[] normal	[] flaccio	ł	[] normal	[] flaccid
	[ne_arms_tone_left] [int(11)] [normal 1, flaccid 2, rigid/spastic 3]	[] rigid/spa	SUC		[] rigid/spast	IC	
	ARMS-Strength						
5.05	[ne_arms_strengt_right] [int(11)]		7 1	114.0		5 1 a a a a a	5 1 de Celt
5.05	[ne_arms_strengt_left] [int(11)]	[] normal	[] defic	CIT	t []normal []deficit		
	[normal 1, deficit 2]						
	LEGS-Tone						
5.06	[ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)]		[] normal [] rigid/spa:	[] flaccic stic	i	[] normal [] rigid/spast	[] flaccid
	[normal 1, flaccid 2, rigid/spastic 3]		[]			[]9	
	LEGS-Strength						
5.07	[ne_legs_strength_right] [int(11)]		[] normal	[]defic	cit	[]normal	[] deficit
	[ne_legs_strength_left] [int(11)]		[]	[]		[]	[]
	[normal 1, deficit 2]						
	Reflexes		Right			Left	
	Biceps						
5.08	[ne_reflexes_biceps_right] [int(11)]		[]present	[]abse	nt	[]present	[]absent
	[ne_reflexes_biceps_left] [int(11)] [present 1, absent 2]						
	Triceps						
5.09	[ne_reflexes_triceps_right] [int(11)]			[]ahaa	nt	[]procont	
5.09	[ne_reflexes_triceps_left] [int(11)]		[]present	[]abse	m	[]present	[]absent
L	[present 1, absent 2]						
5.10	[ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)]		[]present	[]abse	nt	[]present	[]absent
	[present 1, absent 2]						
	Ankle						
5.11	[ne_reflexes_ankle_right] [int(11)]		[]present	[]abse	nt	[]present	[]absent
	[ne_reflexes_ankle_left] [int(11)] [present 1, absent 2]						
L	Iprocent 1, absont 2j		I				
5.12] Yes			2[] No	
	[ne_old_deficit] [int(11)]						
	[Yes 1, No 2]						

Commented [CR22]: If the response is [yes 1] for Q.no.5.01 & 5.02 – specify '1' or '0' [new or worsened 1, unchanged or improved 0]

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 8 of 28

6. MEDICATIONS and MANAGEMENT

6.01		[varchar(20)] [Yes 1, No]No []Unknown	[]Yes, specify:	
	[drug_allergies]					Commented [CR23]: If the response is [Y name
6.02	MEDICATIONS	– Data is saved in "me	dication_mgt.cs	v" file and is in long f	ormat	
Below,	list all medications	s that the participant is p	presently taking or	a regular basis (prior i	o randomization).	
^For (1) Insulin, (2) OHA	As, and (3) Blood press	sure <u>MIXED medi</u>	cations, describe all o	constituents	
separa	tely under "Gene	ric Name" and "Single	e Dose"			
		^List ALL cons Insulin, OHAs,	tituents for BP meds			
Туре	Brand Name [name]	Generic Name	Single Dose	Frequency	Total daily dose	
	[varchar(200)]	[generic_name] [varchar(200)]	[single_dose] [double]	[frequency] [double]	[total_daily_dose] [double]	
nsulin						
OHAs						
3P						
Notio						
Statin						

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 9 of 28

Туре	Brand Name	Generic Name	Single Dose	Frequency	Total daily dose
Other					
Outor					

6.03		Management of diabetes in last 6 months	
		[dibetes_mgt] [varchar(50)]	[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1
	[]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)	Biguanide (Metformin) 2
	[]	Biguanide (Metformin)	Thazolidineodione (Pioglitazone) 3
	[]	Thazolidineodione (Pioglitazone)	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)-
	[]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)	Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
	[]	Glinide (Nateglinide, Repaglinide, Mitiglinide)	Lispro, Aspart, Glulisine insulins (rapid-acting) 6
	[]	Lispro, Aspart, Glulisine insulins (rapid-acting)	Regular Insulins (short-acting) 7
	[]	Regular Insulins (short-acting)	NPH or Lente Insulins (intermediate-acting) 8 Glargine or Determir Insulins (very long-acting) 9
	[]	NPH or Lente Insulins (intermediate-acting)	Other diabetic treatment 10
	[]	Glargine or Determir Insulins (very long-acting)	Dietician or Educator referral 11
	[]	Other diabetic treatment	Weight control or exercise program 12
	[]	Dietician or Educator referral	Home blood glucose monitoring 13
	[]	Weight control or exercise program	
	[]	Home blood glucose monitoring	
6.04		Other medications	
		[other_dibetes_mgt] [varchar(100)]	
	[]	Thaizide or thiazide-like diuretic	
	[]	Other diuretic	

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 10 of 28

[]	ACE inhibitor	Thaizide or thiazide-like diuretic 1
[]	Angiotensin 2 receptor antagonist (ARB)	Other diuretic 2
[]	Beta-blocker	ACE inhibitor 3
[]	Calcium channel blocker (CCB)	Angiotensin 2 receptor antagonist (ARB) 4
[]	Other antihypertensive agent	Beta-blocker 5
[]	Statin	Calcium channel blocker (CCB) 6 Other antihypertensive agent 7
[]	Other cholesterol lowering drug	Statin 8
[]	Aspirin	Other cholesterol lowering drug 9
[]	Other anti-platelet agent	Aspirin 10
[]	Oral anticoagulant	Other anti-platelet agent 11
[]	Nitrates (NOT sublingual)	Oral anticoagulant 12
		Nitrates (NOT sublingual) 13 Hormone replacement therapy 14
	Hormone replacement therapy	Thyroid Agents 15
[]	Thyroid Agents	Oral/inhaled steroids 16
[]	Oral/inhaled steroids	Oral asthma drugs (exclude steroids) 17
[]	Oral asthma drugs (exclude steroids)	Antidepressant 18
[]	Antidepressant	Anti-neuropathy medications (gabapentin, pregabalin,
[]	Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline)	amatryptiline) 19 Erectile Dysfunction drug 20
[]	Erectile Dysfunction drug	Herbal/alternative medicine 21
[]	Herbal/alternative medicine	Vitamins/nutritional supplements 22
[]	Vitamins/nutritional supplements	Other, not listed above 23
[]	Other, not listed above	

7. Randomization

7.01	[]Y	[]N	Completed all of Form C, Part 1 above. If NO, complete now.
7.02	[]Y	[]N	Reviewed Forms and Eligibility with Investigator or Co-Investigator. If NO, review now.
7.03	[]Y	[]N	Patient agrees to continue with the trial If NO, stop here and complete patient status in PARTICIPANT LOG.

If YES for ALL 7.01-7.03, continue to Randomization:

- 1. Information from Participant Log will be required to complete the Randomization.
- Select Randomization option on website <u>www.coe-carrs.phfi.in</u> (CARRS Translation Trial > Randomization) and enter requested data
 - a. Screening Officer Name
 - b. Screening ID (do not include 'S' only numbers)
 - c. Confirm Screening ID (do not include 'S' only numbers)
 - d. Date of Birth (dd/MMM/yyyy)
 - e. Confirm Date of Birth (dd/MMM/yyyy)
 - f. Was the eligibility of the participants to both treatment arms confirmed by investigator?
 - g. Has the participant met all eligibility criteria?

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 11 of 28

- h. Has the participant met any of the exclusion criteria?
- i. Did the participant sign informed consent?

OR IF INTERNET ACCESS NOT POSSIBLE:

Γ

3. Telephone +011 2685-0117/18 and ask for CARRS Translation Trial Randomization

7.04 Result of Randomization: - enter information below & attach print-out from randomization page:

	PARTICIPANT ID:	USE THIS ID in future CRF and eCRF	
[treatr	Allocation: [] Control Group ment_group] [varchar (20)], [INTERVENTION, C	[] Intervention Group	
เตอต	nent_groupj [varchar (20)], [intervention, c	UNI ROLJ	
8.	Signature of Study Physician		
8.01	Name:	Signature:	
8.02	Date Signed: / / / / /	_	
8.03	Complete Participant Log for this patient		
8.04	Check one of the following:		
	$\begin{bmatrix} 1 \text{ Control Group Participant} \rightarrow \text{ send to} \end{bmatrix}$	Research Officer to complete Form C Part 2 (below)	
		nd to Care Coordinator to complete Form C Part 2 (below)	
PART	2: complete by CARE COORDINATOR or	RESEARCH OFFICER	
9.	Demographics		
	•		
9.01	Marital Status	[Single 1, Married 2, Widow/Widower 3, Separated/Divorced 4]	
	[matrial_status] [int], 1[] Single	3[] Widow/Widower	
	2[] Married	4[] Separated/Divorced	
9.02	Occupation		
	[occupation] [int]		
	business owner, staff manager, mid-level farmer, tea	cher, class 1 IAS/services officer, lawyer, 2 Trained, clerical, medium cher, 3 Skilled manual laborer, small business owner, small farmer, 4 Semi- / driver, army jawan, carpenter, fitter, 5 Unskilled manual laborer, landless moloved, 11 Otherl	
		niversity teacher, class 1 IAS/services officer, lawyer	
	2[] Trained, clerical, medium business ow		
	3[] Skilled manual laborer, small business		
		landowner, rickshaw driver, army jawan, carpenter, fitter	
	5[] Unskilled manual laborer, landless lab	orer	
	6[] Homemaker		
	8[] Student 9[] Retired		
	10[] Unemployed		
	11[] Other		
0.00		k 181/A	
9.03	Days per week that you work: [days_per_week_work] [int (1)]	[] N/A [days_per_week_work_na] [int] [(N/A) 1]	Commented [CR24]: If as '1'

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 12 of 28

ponse is [N/A] data is saved

	Hours per day that you work:	[] N/A	Commented [CR25]: If the response is [N/A] data is saved
	[hours_per_day_work] [int(2)]	[hours_per_day_work_na] [int] [(N/A_1)]	as '1'
9.04	TOTAL number of household members:		
	[no_household] [int(2)]		
9.05	Number of children in household:		
	[no_children] [int(2)]		
9.06	Number of adults in household:		
	[no_adult] [int(2)]		
9.07	Number of adults in household earning:		
	[no_adult_earning] [int(2)]		
9.08	During last 12 months, HOUSEHOLD monthly income:		
	[household_income] [int] [<3,000 1, 3,000-10,000 2, 10,000-20,000	0 3, 20,001-30,000 4, 30,001-40,000	
	5, 40,001-50,000 6, >50,000 7, Unknow	n/ Refuse 8]	
	1[]<3,000 4[]20,001-30,000	7[]>50,000	
	2[] 3,000-10,000 5[] 30,001-40,000	8[] Unknown/ Refuse	
	3[] 10,000-20,000 6[] 40,001-50,000		
	During last 12 months, INDIVIDUAL monthly income:	Rupees	
	[individual_income] [int] [<3,000 1, 3,000-10,000 2, 10,000-20,000 3	3, 20,001-30,000 4, 30,001-40,000	
	5, 40,001-50,000 6, >50,000 7, Unknown/ F	Refuse 8]	
	1[]<3,000 4[]20,001-30,000	7[]>50,000	
	2[] 3,000-10,000 5[] 30,001-40,000	8[] Unknown/ Refuse	
	3[] 10,000-20,000 6[] 40,001-50,000		
	3[]10,000-20,000 0[]40,001-30,000		
9.09	Highest Level of Education of Participant:		
3.03	[highest_education] [int] [1 Professional degree/post graduate, 2 Gra	aduato (RA, RSo, RCom, Diploma)	
	3 Secondary School, Standard, 4 Primary Sch		
	5 Literate, no formal education, 6 Illiterate, 7 U		
	1[] Professional degree/post graduate		
	2[] Graduate (BA, BSc, BCom, Diploma)		
	3[] Secondary School, Standard:		
	4[] Primary School (up to class 5), Standard:		
	5[] Literate, no formal education		
	6[] Illiterate		
	7[] Unknown		
9.10	Mother Tongue (Ethnic Origin):	i 5 Kennede - C.Kenhmiri - 7 Meithili	
	[mother_tongue] [int (2)] [1 Assamese, 2 Bengali, 3 Gujarati, 4 Hind 8 Malavalam, 9 Marathi, 10 Puniabi, 11 Sin	dhi, 12 Telugu, 13 Tamil, 14 Urdu, 15 other, specify,	
	16 Unknown]		
	1[] Assamese 10	0[] Punjabi	
		1[] Sindhi	
		2[]Telugu	
	•••	3[]Tamil	
		4[] Urdu	
		5[] Other, specify:	
		mother_tongue_other] [varchar(50)] 6[] Unknown	
	9[] Marathi		
	ə[] marallı		
9.11	Knows English language (check all that apply OR none):		
0.11	[english_language] [int(10)] [(understand 1, speak 2, read/write 3, I	None 4)1	
	1[] understand	····· ·//	
CARRS	Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010	Page 13 of 28	

- 2[] speak 4[] none
- 3[] read/write
- 9.12 Religion:

[religion] [int] [1 Hindu, 2 Muslim, 3 Sikh, 4 Christian, 5 Jain, 6 Buddhism, 7 No religion, 8 other, specify, 9 unknown/refuse]

- 1[] Hindu
- 2[] Muslim
- 3[] Sikh
- 4[] Christian
- 5[] Jain

- [religion_other] [varchar(50)] 9[] unknown/refuse

6[] Buddhism

7[] No religion

8[] other, specify: _

10. Lifestyle - Data is saved in "patient_life_style.csv" and is wide format

10.05	Diet (weekday/ routine day)	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6	
	Meal Time (approximate)	[meal1_ampm] [varchar(6)] [AM or PM]	[meal2_ampm] [varchar(6)] [AM or PM]	[meal3_ampm] [varchar(6)] [AM or PM]	[meal4_ampm] [varchar(6)] [AM or PM]	[meal5_ampm] [varchar(6)] [AM or PM]	[meal6_ampm] [varchar(6)] [AM or PM]	
		_: amPm	Commented [CR26]: Should specify [AM or PM]					
		[meal1_time] [varchar(5)]	[meal2_time] [varchar(5)]	[<mark>meal3_time]</mark> [varchar(5)]	[meal4_time] [varchar(5)]	[meal5_time] [varchar(5)]	[meal6_time] [varchar(5)]	
		 '	 '	+	+'	'		Commented [CR27]: Should specify time of the meal
	Type B=breakfast, L=lunch.	[meal1_type] [varchar(6)]	[meal2_type] [varchar(6)]	[meal3_type] [varchar(6)]	[meal4_type] [varchar(6)]	[meal5_type] [varchar(6)]	[meal6_type] [varchar(6)]	Commented [CR28]: Should specify type of meal i.e.,
	D=dinner, S=snack							B=breakfast, L=lunch, D=dinner, S=snack

10.02 Who decides the meal menu in the household? (check one) [household_meal_menu] [varchar(10)] [(Myself 1, other 2, shared (myself and other) 3)]

[] other (i.e. spouse, relative, hired cook) [] Shared (myself and other) [] Myself

10.03 Who cooks the food in the household? (check one) [household_cook_food] [varchar(10)] [(Myself 1, other 2, shared (myself and other) 3)]

[] other (i.e. spouse, relative, hired cook) [] Myself [] Shared (myself and other)

10.04	Physical Activity (in leisure time) in average			
	week	Days per week	Total time per day	
			Hour(s)	Minutes
	Vigorous	[<mark>pa_vigorous_days_per_week</mark>]	[<mark>pa_vigorous_total_hr]</mark>	[pa_vigorous_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Moderate	[pa_moderate_days_per_week]	[pa_moderate_total_hr]	[pa_moderate_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Mild (Walking)	[<mark>pa_walking_days_per_week</mark>]	[pa_walking_total_hr]	[pa_walking_total_min]
		[int(11)]	[int(11)]	[int(11)]

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 14 of 28

.05	Ever use tobacco ever_use_tobacco] [int(11)]	[Yes=1; No=2]	[] Y Continue be [] N Skip to 10.0	
	Current regular use Y N	Past regular use Y N	Number of years used	Current/past Average Quantity per day
Cigarette	[][] [cigarette_regular_use] [int(11)] [Yes=1; No=2]	[] [] [cigarette_past_use] [int(11)] [Yes=1; No=2]	[cigarette_no_of_year] [int(11)]	[cigarette_qty_per _day] [int(11)]
Beedi	[] [] [beedi_regular_use] [int(11)] [Yes=1; No=2]	[] [] [beedi_past_use] [int(11)] [Yes=1; No=2]	[beedi_no_of_year] [int(11)]	[beedi_qty_per_da y] [int(11)]
Cigar/Pip e	[] [] [cigar_pipe_regular_use] [int(11)] [Yes=1; No=2]	[] [] [cigar_pipe_past_use] [int(11)] [Yes=1; No=2]	[cigar_pipe_no_of_year] [int(11)]	[cigar_pipe_qty_p er_day] [int(11)]
chewing tobacco (in paan masala, paan, other mix)	[] [] [chewing_tobacco_regul ar_use] [int(11)] [Yes=1; No=2]	[] [] [chewing_tobacco_pas t_use] [int(11)] [Yes=1; No=2]	[chewing_tobacco_no_ of_year] [int(11)]	[chewing_tobacco _qty_per_day] [int(11)]
Other:	[] [] [other_regular_use] [int(11)] [Yes=1; No=2]	[] [] [other_past_use] [int(11)] [Yes=1; No=2]	[other_no_of_year] [int(11)]	[other_qty_per_da y] [int(11)]

 10.06
 Ever drink alcohol
 [] Y
 Continue below
 [Yes=1; No=2]

 [] ever_drink_alcohol]
 [int(11)]
 [] N
 Skip to Section 11
 Commented [CR30]: If the response is[No 2] skip to Q.no.11 (Selfcare)

[]Y []N	Currently drink alcohol once a week or more (for most weeks in past year)
	[currt_drink_alcohol] [int(11)] [Yes=1; No=2]
[]Y []N	Used to drink alcohol regularly in the past
	[drink_alcohol_regularly_past] [int(11)] [Yes=1; No=2]
	Number of years of alcohol use
	[no_year_alcohol] [int(11)] [No data in this field]
	Average days per week of alcohol use (current/past)
	[aveg_day_week_drink] [int(11)]
	Average drinks per day (current/past)
	One drink: wine=100 ml, spirit=30 ml, beer=330 ml
	[aveg_per_day_drink] [int(11)] [aveg_drink_wine_week] [int(11)] [aveg_drink_spirits_week] [aveg_drink_beer_week] {doubt in this 2 fields}
	Most drinks in one day in past 3 months (0 if not currently drinking)
	[aveg_most_drink] [int(11)]

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 15 of 28

Commented [CR29]: If the response is [No 2] skip to Q.no.10.06

11. Self-Care - Data saved in "patient_self_care.csv" & "patient_selfcare_form_c.csv" and is in long format

The questions below ask you about your diabetes self-care activities during the past 7 days.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET									
11.01	On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?		1	2	3	4	5	6	7
11.00	[self_care_id=2] [int(11)] [0 1 2 3 4 5 6 7]								
11.02	servings of fruits and vegetables?		1	2	3	4	5	6	7
[self_care_id=3] [int(11)] [0 1 2 3 4 5 6 7]									
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products? [self_care_id=4] [int(11)] [0 12 3 4 5 6 7]	0	1	2	3	4	5	6	7
11.04	4 On how many of the last SEVEN DAYS did you space eating meals evenly through the day?			2	3	4	5	6	7
	[self_care_id=5] [int(11)] [0 1 2 3 4 5 6 7]								
EXERC	ISE								
11.05	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)			2	3	4	5	6	7
	[self_care_id=6] [int(11)] [0 1 2 3 4 5 6 7]								
11.06	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
	[self_care_id=7] [int(11)] [0 1 2 3 4 5 6 7]								
BLOOD	SUGAR TESTING								
11.07	Are you testing your blood sugar as recommended by your health care provider?		0 [] No 1 [] Yes 2 [] N/A (skip to 11.09)						
	[self_care_id=9] [int(11)] [Yes 1, No 0, N/A -1]	''	116	5 2	.[]		(SKIP to 11.09)		
11.08	.08 On how many of the last SEVEN DAYS did you test your blood sugar?		1	2	3	4	5	6	7
	[self_care_id=8] [int(11)] [0 1 2 3 4 5 6 7]								
MEDIC	ATIONS								
11.09	On how many of the last SEVEN DAYS, did you take your recommended <u>diabetes medication</u> ? (pills and/or insulin) [self_care_id=10] [int(11)] [0 12 3 4 5 6 7]			2	3	4	5	6	7
11.10	1.10 On how many of the last SEVEN DAYS did you check your feet?			2	3	4	5	6	7
	[self_care_id=11] [int(11)] [0 1 2 3 4 5 6 7]								-
ТОВАССО									
11.11	Ever smoke regularly? (most days of the week)								
	$[self_care_id=12] [int(11)] [never 0, quit 1, Yes 2] [if quit 1] \rightarrow [quit smoking year] [varchar(20)] [1] [1] Qu$						_ (MN	1M/yy	yy)
	[if yes 2] → [smoke_per_day] [int(11)]								

Commented [CR31]: In Self-care section data is saved in 2 files 1. "patient_self_care.csv" & 2." patient_selfcare_form_c.csv and unique ID is "Self_care_id "

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 16 of 28

Commented [CR32]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

11.12	Ever chew tobacco regularly? (most days of the week) [self_care_id=13] [int(11)] [never 0, quit 1, Yes 2] [if quit 1] → [quit_tobacco_year] [varchar(20)] [if yes 2] → [packet_per_day] [int(11)]		/ (MMM/yyyy) # packets per day:		CR33]: If the response is [quit 1] specify the year s 2] specify no. packet per day
11.13	If you smoke or chew tobacco, at your last doctor's visit, did anyone counsel you about stopping or refer you to counseling? [self_care_id=14] [int(11)] [N/A 0, yes 1, no 2]	0[]No 1[]Yes	2[]N/A		
ALCOH	IOL				
11.14	Drink alcohol regularly? (at least once a week for mo in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] [never 0, yes 1]	st weeks	0 [] No 1 [] Yes, # drinks per day:		
07050	$[if yes 1] \rightarrow [drink_per_day] [int(11)]$			Commented [0 drink per day	CR34]: If the response is [yes 1] specify no.
STRES					
11.15	How often do you feel stress (from work, responsib [] daily [] few times a week [self_care_id=16] [int(11)] [daily 1, few times a week 2, few tii	[] few ti	mes a month [] never		CR35]: Responses at backend for this variable are
11.16	How are you coping with stress? [] very well] moderate [] with difficulty [[self_care_id=17] [int(11)] [very well 1, moderate 2, with diffic		ategory for '0' CR36] : Responses at backend for this variable are		
				saved as [0 1 2 3 d but, there is no ca	
12.	EQ-5D - Data saved in "eq_5d.csv" and is in wide form	at			
Place a	tick in one box in each group below for the statement the	at best desc	ribes your own health state today.		
12.01	Mobility [I have no problems in walking about 1, II] [mobility_id] [int (11)] I am confined to bed 3] 1 I have no problems in walking about 2 I have some problems in walking about 2 I have some problems in walking about 2	have some pro	blems in walking about 2,		

3 I am confined to bed

12.02 Self-Care [I have no problems with self-care 1, I have some problems with self-care 2,

[self_care_id] [int(11)] I am unable to wash or dress myself 3]

- 1 I have no problems with self-care
- 2
 I have some problems with self-care
- $3 \Box$ I am unable to wash or dress myself

12.03 Usual Activities (e.g. work, study, housework, family or leisure activities)

[usual_activities] [int(11)] [I have no problems with performing my usual activities 1,

- I have some problems with performing my usual activities 2,
- I am unable to perform my usual activities 3]
- 1 I have no problems with performing my usual activities
- 2 \square I have some problems with performing my usual activities
- 3 🗆 I am unable to perform my usual activities

12.04 Pain/Discomfort

[pain_discomfort] [int(11)] [I have no pain or discomfort 1, I have moderate pain or discomfort 2, I have extreme pain or discomfort 3]

- 1 □ I have no pain or discomfort
- 2 \Box I have moderate pain or discomfort
- $3 \square I$ have extreme pain or discomfort

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 17 of 28

12.05 Anxiety/Depression

[anxiety_depression] [int(11)] [I am not worried or depressed 1, I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]

- 1 🗆 I am not worried or depressed
- 2 \Box I am moderately anxious or depressed
- 3 🗆 I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.



CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

13. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale. How satisfied are you with your current treatment? 13.01 [current_treatment] [int] [0, 1, 2, 3, 4, 5, 6] Very satisfied Very dissatisfied 2[] 1[] 6[] 5[1 4[] 3[1 0[] 13.02 How often have you felt that your blood sugars have been unacceptability high recently? [blood_sugar_high] [int] [0, 1, 2, 3, 4, 5, 6] Most of the time None of the time 5[] 3[] 2[] 6[] 4[] 1[] 0[] 13.03 How often have you felt that your blood sugars have been unacceptability low recently? [blood_sugar_low] [int] [0, 1, 2, 3, 4, 5, 6] Most of the time None of the time 5[] 4[] 3[] 2[] 1[] 0[] 6[] 13.04 How convenient have been finding your treatment to be recently? [convienent_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very convenient Very inconvenient 6[] 5[] 4[] 3[] 2[] 1[] 0[] How flexible have you been finding your treatment to be recently? 13.05 [flexible_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very inflexible Very flexible 6[] 5[] 4[] 3[] 2[] 1[] 0[] 13.06 How satisfied are you with understanding of your diabetes? Very satisfied Very dissatisfied 4[] 3[] 2[] 6[] 5[] 1[] 0[] How satisfied would you be to continue with your present form of diabetes treatment? 13.07 [present_dib_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very satisfied Very dissatisfied 3[] 2[] 1[] 5[] 4[] 0[] 6[] Would you recommend this form of treatment to someone else? 13.08 [recommend_form] [int] [0, 1, 2, 3, 4, 5, 6] Yes, I would No, I would definitely definitely NOT recommend recommend this treatment this treatment 4[] 3[] 2[] 1[] 6[] 5[] 0[]

14. Health Utilities Index

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] [1, 2, 3, 4]

- 1 a. Able to see well enough without glasses or contact lenses
- 2 b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses

4□ d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] [1, 2, 3, 4]

- 1 a. Able to see well enough without glasses or contact lenses
- 2 b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses

4 d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] [1, 2, 3, 4, 5]

- 1 a. Able to hear what was said without a hearing aid
- 2D b. Able to hear what was said with a hearing aid
- 3 c. Unable to hear what was said even with a hearing aid.
- 4 d. Unable to hear what was said, but did not wear a hearing aid
- 5 e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a guiet room?

[other_person_conversation] [int] [1, 2, 3, 4, 5]

- 1 a. Able to hear what was said without a hearing aid
- 2D b. Able to hear what was said with a hearing aid
- 3 c. Unable to hear what was said even with a hearing aid
- 4 d. Unable to hear what was said, but did not wear a hearing aid
- 5D e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] [1, 2, 3, 4]

- 1 a. Able to be understood completely
- 2 b. Able to be understood partially 3 c. Unable to be understood
- 4 d. Unable to speak at all
- 14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] [1, 2, 3, 4]

- 1 a. Able to be understood completely.
- 20 b. Able to be understood partially.
- 3 c. Unable to be understood.
- 4 d. Unable to speak at all.

14.07. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling] [int] [1, 2, 3, 4, 5]

- 1 a. Happy and interested in life
- 2D b. somewhat happy
- 3 c. somewhat unhappy
- 4□ d. Very unhappy
- 5 e. So unhappy that life was not worthwhile

CARRS Translation Trial; Form C - Baseline_Randomization v1.4-3DEC2010

Page 20 of 28

14.08. Which one of the following best describes the pain and discomfort you have experienced during the past 4 weeks?

[discomfort_exp] [int] [1, 2, 3, 4, 5]

1□ a. Free of pain and discomfort

2 b. Mild to moderate pain or discomfort that prevented no activities.

3 c. Moderate pain or discomfort that prevented a few activities

4 d. Moderate to severe pain or discomfort that prevented some activities

5 e. Severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] [1, 2, 3, 4, 5, 6]

1 a. Able to walk around the neighborhood without difficulty, and without walking equipment

2 b. Able to walk around the neighborhood with difficulty; but did not require walking equipment

or the help of another person

3 c. Able to walk around the neighborhood with walking equipment, but without the help of another person 4 d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood

5 c. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood

6D f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.)
[hands_finger] [int] [1, 2, 3, 4, 5, 6]

1□ a. Full use of hands and ten fingers

2 b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person

3 . Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)

4 d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)

 $5\square$ e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not

independent even with use of special tools)

6 f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] [1, 2, 3, 4]

 $1\square$ a. Able to remember most things

2□ b. Somewhat forgetful

3□ c. Very forgetful

4□ d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] [1, 2, 3, 4, 5]

- 1 a. Able to think clearly and solve day to day problems
- 2D b. Had a little difficulty when trying to think and solve day to day problems
- $3\square$ c. Had some difficulty when trying to think and solve day to day problems
- $4\square$ d. Had great difficulty when trying to think and solve day to day problems
- $5\square$ e. Unable to think or solve day to day problems

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 21 of 28
14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] [1, 2, 3, 4]

1□ a. Eat, bathe, dress and use the toilet normally

2D b. Eat, bathe, dress and use the toilet independently with difficulty

3 c. Required mechanical equipment to eat, bathe, dress or use the toilet independently

4 d. Required the help or another person to eat, bathe, dress or use the toilet

14.14. Which one of the following best describes how you have been feeling during the past 4 weeks? [feeling_health_utility] [int] [1, 2, 3, 4]

1 a. Generally happy and free from worry

2 b. occasionally fretful, angry, irritable, anxious or depressed

3 c. often fretful, angry, irritable, anxious or depressed

4 d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

[discomfort_health_utility] [int] [1, 2, 3, 4, 5]

1 a. Free of pain and discomfort

2 b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities

3 C. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities

4 d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief

5 e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15. Processes of Care

In the past 12 months, how often did the following occur (EXCLUDE current visit):

		Indicate number	Month of last visit/test/exa (MMM/yyyy)	ım
15.01	Clinic Visits [fpc_clinic_visit_indicate_no] [int(11)]		/	[]unknown
	[fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] [-1]			
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] [-1]		/	[]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)] [fpc_cholestrol_testing_unknown] [int(11)] [-1]		/	[]unknown
15.04	Foot Exam at clinic [fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] [-1]		/	[]unknown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] [-1]		/	[]unknown

Commented [CR37]: For Q.Nos. 15.01 – 15.09, specify Indicate number, Month of last visit & unknown If response is [unknown] data is saved as '-1'

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 22 of 28

15.06 Microalbuminutia check []uminutia check []uminutia check []uminutia check []uminutia 15.07 ECG					
Ipc_microal_check_indicate_no] [int(11)] Ipc_microal_check_unknown] [int(11)] Ipc_microal_check_unknown] [int(11)] 15.07 ECG [ipc_microal_check_unknown] [int(11)] Ipc_ecg_microal_check_unknown] [int(11)] 15.08 Dental Exam [ipc_microal_check_unknown] [int(11)] Ipc_ecg_exam_unknown] [int(11)] Ipc_ecg_exam_unknown] [int(11)] 15.09 Dental Exam Ipc_ecg_exam_unknown] [int(11)] Ipc_ecd_etaia_exam_undicate_no] [int(11)] Ipc_ecd_etaia_exam_undicate_no] [int(11)] 15.09 Dietician/visit_unknown] [int(11)] Ipc_ecd_etaia_exam_undicate_no] [int(11)] Ipc_ecd_etaia_exam_undicate_no] [int(11)] 15.00 Dietician/visit_unknown] [int(11)] Ipc_ecd_etaia_exam_undicate_no] [int(11)] Ipc_ecd_etaia_visit_unknown] [int(11)] 15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care?	15.06	Microalbuminuria check		/	[]unknown
Ifpc.microal.check.unknown [init13] [init13] 15.07 ECG []unknow 15.07 ECG []unknow 15.08 Decidate_nol_linit[1]					_ [].
ipc_microal_check_unknown[int(13]].+1) 15.07 ECG ipc_ecg_indicate_no] [int(13)] ipc_ecg_exam_unknown[int(13)].+1) 15.08 Dental Exam ipc_dental_exam_unknown[int(13)].+1) 15.08 Dental Exam ipc_dental_exam_unknown[int(13)].+1) 15.09 Dental Exam ipc_dental_exam_unknown[int(13)].+1) 15.00 Dental Exam ipc_dental_exam_unknown[int(13)].+1) 15.00 Dental Exam ipc_dental_exam_unknown[int(13)].+1) 15.00 Other than your current diabetes Education ipc_dental_exam_unknown[int(13)].+1) 15.01 Other than your current diabetes physician, how many other doctors do you see regularly for care?			(15)]		
15.07 ECG []unknow 15.07 ECG []unknow 15.07 ECG []unknow 15.08 Dental Exam []unknow 15.09 Detriction []unknow 15.00 Detriction []unknow 15.01 Cetral exam []unknow 15.02 Detriction []unknow 15.03 Detriction []unknow 15.04 Detriction []unknow 15.07 Detriction []unknow 15.10 Total time spend commuting to clinic – ONE WAY					
ipc_seg_indicate_noj [ini(1)] ipc_seg_month_of_visit [varchar(15)] ipc_seg_exam_unknown] [ini(11)] [-1] ipc_dental_exam_indicate_noj [ini(11)] 15.08 Dental Exam [ipc_dental_exam_unknown] [ini(11)] ipc_dental_exam_unknown] [ini(11)] ipc_dental_exam_unknown] [ini(11)] ipc_dental_exam_unknown] [ini(11)] 15.09 Dietician/Diabetes Education ipc_dental_exam_unknown] [ini(11)] ipc_dental_exam_unknown] [ini(11)] ipc_dentian_visit_unknown] [ini(11)] ipc_dentian_visit_unknown] [ini(11)] ipc_dentian_visit_unknown] [ini(11)] ipc_dentian_visit_unknown ipn_dentian_visit_unknown] [ini(11)]<	15.07			1	[]unknown
ipc_eeg_month_of_visit[varchar(15)]	10.01			/	
Ifpc_ecg_exam_unknown] [int(11)] [+1]					
15.08 Dental Exam [] unknowi Ifpc_dental exam_indicate_nol [int(11)] [] unknowi Ifpc_dental_exam_unknowni [int(11)] [] unknowi Ifpc_dental_exam_unknowni [int(11)] [] unknowi Ifpc_dental_exam_unknowni [int(11)] [] unknowi Ifpc_detician/Diabetes Education [] unknowi [] unknowi Ifpc_detician/visit_month_of_visit[varchar(15)) [] unknowi [] unknowi Ifpc_detician/Diabetes Education [] unknowi [] unknowi Ifpc_detician/Diabetes Physician, how many other doctors do you see regularly for care? [] unknowi [] forther doctors_count [] unknowi [] unknowi [] Ital Total time spend tor lab tests, include waiting (if done same day) [] min [] Ital Ital tests, include waiting (if done same day) [] min					
Ifpc_dental_exam_indicate_nol_[int(11)] Image:	15.08			/	[]unknown
Ifpc_dental_exam_month_of_visit] (varchar(15)) Image: the symbol of					
Ipc_dental_exam_unknown [int(11)] /-1/ 15.09 Dietcian/Diabetes Education Ipc_dietcian_visit_indicate_no] [int(11)] Ipc_detician_visit_unknown] [int(11)] Ipc_detician_visit_unknown] [int(11)] Ipc_detician_visit_unknown] [int(11)] Ipc_detician_visit_unknown] [int(11)] Ipp_detician_visit_unknown] [int(11)] On average: [int(11)] 15.11 Total time spend commuting to clinic – ONE WAY			15)]		
15.09 Dietician/Diabetes Education [] unknow Ifpc_dietician_visit_indicate_no] [[nt(11)]] [] unknow Ifpc_dietician_visit_month_of_visit] [unc(11)] [] unc(11) On average: [] unc(11)] [] unc(11) Chare_doctors_count] [[[nt(11)]] [] minint Ifs.11 Total time spend commuting to clinic – ONE WAY					
Ifpc_dietician_visit_month_of_visit[[varchar(15)] Ifpc_dietician_visit_month_of_visit[[varchar(15)] Ifpc_dietician_visit_unknown] [int(11)] [r1] Iffico_dietician_visit_unknown] [int(11)] [r1] 15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care?	15.09			1	[]unknown
Ipc_dietician_visit_month_of_visit[verchar(15)] Ipp_dietician_visit_month_of_visit[verchar(15)] Ipp_dietician_visit_month_of_visit[verchar(15)] Ipp_dietician_visit_month_of_visit[verchar(15)] Ipp_dietician_visit_month_of verchar(20)] Ipp_dietician_visit_month_of_visit[verchar(20)] Ipp_dietician_visit_month_of_visit[verchar(20)] Ipp_dietician_visit_month_of verchar(20)] Ipp_dietician_visit_month_of verchar(20)] Ipp_dietician_visit_month_of verchar(20)] Ipp_dietician_visit_month_of verchar(20)]	10.00			/	
(fpc_dietician_visit_unknown] [int(f1)] 15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care? [other_doctors_count] [int(f1)] On average: 15.11 Total time spend commuting to clinic – ONE WAY			15)]		
15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care? [other_doctors_count] [int(11)] On average:					
[other_doctors_count] [int(11)] On average:	15 10 0		w many other doctors	do vou see regula	rly for care?
On average: 15.11 Total time spend commuting to clinic – ONE WAY	10.10 0		and the second second	do you see regula	
15.11 Total time spend commuting to clinic – ONE WAY					
[time_commuting] [int(11)] 15.12 Total time spend for lab tests, include waiting (if done same day)min [lab_test] [int(11)] min 15.13 Total time spend waitingfor consultationmin min [wait_consult] [int(11)] min 15.14 Total time spend in-person with doctormin min [in_person_doc] [int(11)] min min 15.15 Total time with dietician, nurse or clinic-staff receiving self-care educationmin min [self_care_edu] [int(11)] min min 15.15 Total time with dietician, nurse or clinic-staff receiving self-care educationmin min [self_care_edu] [int(11)] min min 15.16 Other time for check-out, getting medications, etc (at end of visit)min min [other_time] [int(11)] min min 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) min [other_time] [int(11)]		8	MAX		min
15.12 Total time spend for lab tests, include waiting (if done same day)	15.11		VAT		111111
[lab_test] [int(11)]	45 40				
15.13 Total time spend waitingfor consultation min [wait_consult] [int(11)] 15.14 Total time spend in-person with doctor min [in_person_doc] [int(11)] 15.15 Total time with dietician, nurse or clinic-staff receiving self-care education min [self_care_edu] [int(11)] min 15.16 Other time for check-out, getting medications, etc (at end of visit) min [other_time] [int(11)] min 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder for next visit, referral or lab investigation (at current visit) 2] Written reminder for next visit, referral or lab investigation (at current visit) 31] Phone call for upcoming appointment (clinic or referral) 41] Phone call for upcoming appointment (clinic or referral) 51] Phone call to go for lab investigations 61] Mailing for missed appointment (clinic or referral) 71] Mailing for missed appointment (clinic or referral) 72] Mailing for missed appointment (clinic or referral) 81] Mailing for missed appointment (clinic or referral) <t< td=""><td>15.12</td><td>· · ·</td><td>(ir done same day)</td><td></td><td> min</td></t<>	15.12	· · ·	(ir done same day)		min
[wait_consult] [int(11)] 15.14 Total time spend in-person with doctor min [in_person_doc] [int(11)]					
15.14 Total time spend in-person with doctor min [in_person_doc] [int(11)] 15.15 Total time with dietician, nurse or clinic-staff receiving self-care education min [self_care_edu] [int(11)] 15.16 Other time for check-out, getting medications, etc (at end of visit) min [other_time] [int(11)] 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 15.17 What type of neminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 15.17 What type of neminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 15.17 Written reminder for next visit, referral or lab investigation (at current visit) 2] Written reminder for next visit, referral or lab investigation (at current visit) 3] Phone call for upcoming appointment (clinic or referral) 4] Phone call to go for lab investigations 9] other, specify:	15.13				min
[in_person_doc] [int(11)] 15.15 Total time with dietician, nurse or clinic-staff receiving self-care educationmin					
15.15 Total time with dietician, nurse or clinic-staff receiving self-care educationmin	15.14				min
[self_care_edu] [int(11)] 15.16 Other time for check-out, getting medications, etc (at end of visit)min [other_time] [int(11)] 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 1] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2 2] Written reminder for next visit, referral or lab investigation (at current visit) 3] Phone call for upcoming appointment (clinic or referral) 4] Phone call if missed appointment (clinic or referral) 5] Phone call to go for lab investigations 6] Mailing for upcoming appointment (clinic or referral) 7] Mailing to go for lab investigations 9] other, specify:					
15.16 Other time for check-out, getting medications, etc (at end of visit)min	15.15		eceiving self-care edu	ucation	min
[other_time] [int(11)] 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 1] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9] other, specify:		· · ·			
 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 1 [] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:	15.16		etc (at end of visit)		min
[type_of_reminder] [varchar (20)] 1 [] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call to go for lab investigations 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:		[other_time] [int(11)]			
1 [] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:	15.17	What type of reminders do you receive from the	he clinic for your care	? (check all that ap	oply)
2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call if missed appointment (clinic or referral) 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:		[type_of_reminder] [varchar (20)]			
3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call if missed appointment (clinic or referral) 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:	1[]Ve	erbal reminder for next visit, referral, or lab inve	estigation (at current	visit)	
4 [] Phone call if missed appointment (clinic or referral) 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:	2[]W	ritten reminder for next visit, referral or lab inve	estigation (at current	visit)	
5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:	3[]Pł	hone call for upcoming appointment (clinic or r	eferral)		
6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:	4[]Pł	hone call if missed appointment (clinic or refer	al)		
7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:	5[]Pł	hone call to go for lab investigations			
8 [] Mailing to go for lab investigations 9 [] other, specify:	6[]M	ailing for upcoming appointment (clinic or refe	ral)		
9 [] other, specify: [other_reminder] [varchar (20)] 16. Costs of Care 16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR: Outpatient visits? Inpatient care? % Out-of-pocket% Out-of-pocket	7[]M	ailing for missed appointment (clinic or referral)		
[other_reminder] [varchar (20)] 16. Costs of Care 16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR: Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket	8[]M	ailing to go for lab investigations			
[other_reminder] [varchar (20)] 16. Costs of Care 16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR: Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket	9[]ot	her, specify:			
16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR: Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket	-				
Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket	16.	Costs of Care			
% Out-of-pocket% Out-of-pocket	16.01	What are your sources of finance (give percent	ntages, indicate '0' if	not used) FOR:	
	Outpatie	ent visits?	Inpatient care?		
CARRS Translation Trial; Form C – Baseline Randomization v1.4-3DEC2010 Page 23 of 28	%	6 Out-of-pocket	% Out-of-p	ocket	
	CARRS 1	Franslation Trial: Form C – Baseline Randomization	1.4- 3DEC2010	Par	ie 23 of 28

[out_of_pocket_opd] [double] % Employer Insurance [employer_insurance_opd] [double] % Private Insurance	[out_of_pocket_ipd] [double] % Employer Insurance [employer_insurance_ipd] [double] % Private Insurance
[private_insurance_opd] [double] % Government insurance, non-job based	[private_insurance_ipd] [double] % Government insurance, non-job based
[govt_insurance_opd] [double]	[govt_insurance_ipd] [double]
% Other, please specify:	% Other, please specify:
[other_opd] [double]	[other_ipd] [double]
[other_details_opd] [varchar(200)]	[other_details_ipd] [varchar(200)]
= 100 % total	=100 % total

OUTPATIENT CARE

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1 year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization. EXCLUDE current visit.

- 16.03 How many days, including half days, did you miss from work

for outpatient visits in the past 1 year? _____ days [] N/A

[days_miss_work] [int(11)] [days_miss_work_na] [int(11)] [1]

16.04 List all persons who accompanied you to outpatient visits in the past 1 year: This data is in file "patient_accompained_visit" & is in long format

Person Relation (e.g. father)	Occupation	Monthly salary	Number visits accompanied
[person_relation]	(number*)	[monthly_salary]	[number_of_visit]
	[occupation]		

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item		Number	Average cost
			of times	One-time (Rupees)
16.05	Consultatio	on Fee		
	[con_fee_f	rq] [int(11)] [avg_con_fee] [double]		
16.06	Lab Tests	(HbA1c, blood glucose, urine check)		
	[lab_test_f	rq] [int(11)] [avg_lab_test] [double]		
16.05	Eye Exam			
	[eye_eam_	_frq] [int(11)] [avg_eye_exam] [double]		
16.06	ECG			
	[ecg_frq]	int(11)] [avg_ecg_fee] [double]		
16.07	Medicines	(tablets, insulin)		
	[med_frq]	[int(11)] [avg_med_fee] [double]		

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 24 of 28

Commented [CR38]: One more variable available for questions 16.05 to 16.12 "Total cost" and values also stored for this variable

16.08	Supplies (including glucose strips, gauze, sterile solution,	
	etc.)	
	[supply_frq] [int(11)] [avg_supply_fee] [double]	
16.09	Transportation	
	[transport_frq] [int(11)] [avg_transport] [double]	
16.10	Food (personal)	
	[food_personal_frq] [int(11)] [avg_food_personal] [double]	
16.11	Additional cost for escort(s) (e.g. food)	
	[escorts_freq] [int(11)] [avg_escorts] [double]	
16.12	Other out-of-pocket expenses	
	[outpocket_frq] [int(11)] [avg_outpocket_exp] [double]	
	· · · · · · · · · · · · · · · · · · ·	

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetesrelated complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year?

[hospital_emergency] [int(11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below – (Make sure that visits listed below equals total number listed in 16.13) When providing time, include half-days. This data is in file "patient_hospitalization_visit" & is in long format

	TYPE	Days of	Hospital	Cost	Transpo	ortation	Food Cost	Additional	Person(s) accompanied (Escort) – list all		
	1=	stay	including		Cost,		[food_cost]	Escort(s) Cost				
	Hospitalization,	-	medicine/		includin	a	[]	[escorts_cost]				
		[ddiddoi]				-			Deletier	Occurretien	Manthly Calany	Deve eccentration
	NO surgery		supplies		ambula				Relation	Occupation	Monthly Salary	Days accompanied
	2= Surgery		(total	stay)	fees	(total			[person_accompained]	(number*)	[monthly_salary]	[days_person_accompained]
	3= Emergency		[hospital_	_cost]	stay)					[occupation]		
	Room [reason]				[transp	ort]						
1												
2												
2												
3												
4												

5						
_						
6						

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

17. Other Contacts

This data is confidential

Please list 2 contacts who do not live with you and would know where and how we can contact you. *mandatory fields

17.01	Contact 1	
Name		First:*
		Middle:
		Last:*
Mailing Ad	ldress	Address 1:*
		Address 2:
		City:*
		Pin code:*
		State.*
Mobile*		91
Phone 2		
Email ID		
Relation (e.a. father. friend) *	

17.02	Contact 2	
Name		First:*
		Middle:
		Last.*
Mailing A	ddress	Address 1:*
		Address 2:
		City:*
		Pin code:*
		State:*
Mobile*		91
Phone 2		
Email ID		
Relation (e.g. father, friend) *	

18. Care Coordinator/Research Officer Signature

18.01 Name: _

_____ Signature:

18.02 Date Signed: ___ / __ __ / ___ __ / _____

18.03 DSS Instructions:

(1) Enroll patient in DSS \rightarrow Login. Select **Enroll patient** from left panel. Enter information and click on **Enroll** at bottom of page.

(2) Enter rest of Forms B and Form C in eCRFs found on patient main page.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 28 of 28

FORM I.c – Intermediate Visit_Control CARRS Translation Trial Research Officer	Participant ID: [participant_id] [varchar(20)] Participant Initials: Date of Visit (dd/MMM/yyyy): / / / [dateofvisit] [date]
 Form I.c – Data is saved in the file "patient_form All dates dd/MMM/yyyy (e.g. 31/DEC/2010) Place cross [X] in the appropriate boxes. Write nu See Form Completion Notes, for definitions and e Store copies of available source documents (SD); 	Data entry by: [dataentry_by] [varchar(50)] Initials parameters /

• The Research Officer may only obtain information AFTER participant visit, from the visit records. Fill out all information that is **applicable/available**. Indicate NAV if not available.

1.01	Reason for Visit	1 [] Routine	2 [] Other	3 [] NAV	Commented [CR1]: No data is saved in this field
1.02	Mark [X] for all	1] heart rate		(beats/min)	Commented [OK 1]. No data is saved in this field
	measures,	[is_heart_rate] [varchar(1	0)] [on]	[heart_rate] [int(11)]	Commented [CR2]: If we select the response to the question
	investigations, or	2 [] blood pressure		/(mmHg)	1.02 (1-23) it is saved as "on" otherwise "blank"
	exams done at this visit. Include values if	[is_blood_pressure] [varc	har(10)] [on]	[blood_pressure_h_avg] / [blood_pressure_l_	avgl
	available.			[int(11)] [int(11)]	
		3 [] weight		(kg)	
		[is_weight] [varchar(10)]	[on]	[weight] [double]	
		4 [] HbA1c		%	
		[is_hba1c] [varchar(10)]	[on]	[hemoglobin_a1c] [double]	
		5 [] Fasting blood glucos	se (venous)		
		[is_fbg] [varchar(10)] [on	1	[fasting_blood_glucose] [double]	
		6 [] Post-prandial blood	glucose (venous)	(mg/dL)	
		[is_ppbg] [varchar(10)] [d	on]	[post_prandial_blood_glu] [double]	
		7 [] Random blood gluco	ose (capillary)	(mg/dL)	
		[is_pbg] [varchar(10)] [or	ŋ]	[random_blood_glucose] [double]	
		8 [] Sodium		(mEq/L)	
		[is_sodium] [varchar(10)]	[on]	[sodium] [double]	
		9 [] Potassium		(mEq/L)	
		[is_potassium] [varchar(1	0)] [on]	[potassium] [double]	
		10 [] Total cholesterol		(mg/dL)	
		[is_total_cholesterol] [var	char(10)] [on]	[total_cholesterol] [double]	
		11 [] HDL cholesterol		(mg/dL)	
		[is_hdl_cholesterol] [varcl	nar(10)] [on]	[hdl_cholesterol] [double]	
		12 [] LDL cholesterol		(mg/dL)	
		[is_ldl_cholesterol] [varch	ar(10)] [on]	[Idl_cholesterol] [double]	
		13 [] Triglycerides		(mg/dL)	
		[is_tryglycerides] [varchai		[triglycerides] [double]	
		14 [] Creatinine (serum)		(mg/dL)	
		[is_creatinine] [varchar(10		[creatinine_mg] [double]	
		15 [] Urine microalbumin		(mg/L)	
		[is_albuminuria] [varchar		[albuminuria] [double]	
		16 [] Urine albumin:crea		(mg/g) [s_albumin_mg] [double]	
		[is_albumin_mg] [varcha			
		17 [] Other blood test, sp	,	[other_blood_test] [varchar(100)]	
		[is_other_blood_test] [var	char(10)] [on]		
		18 [] ECG		[acc] [versher(20)]	
		[is_ecg] [varchar(10)] [or	-	[ecg] [varchar(20)]	Commented [CR3]: No data is saved in this field
		19 [] Foot exam (monofi			
		[is_foot_exam] [varchar(1	U)] [on]		
		20 [] Biothesiometry			
		[is_biothesimetry] [varcha			
		21 [] Ankle Brachial Inde			
		[is_ankle_brachaial] [var			
		22 [] Eye Exam (fundoso			
		[is_eye_exam] [varchar(
	1	23 [] Other Exam, specif	V:	1	

CARRS Translation Trial; Form Dc – Intermediate Visit_Control v1.2-17JUL2010

	-		
		[is_other_exam] [varchar(10)] [on]	[other_exam] [varchar(100)]
1.03	Mark [X] all details of management plan at this visit	[Is_other_exam] [varchar(10)] [on] 1 [] Change in medications for diabetes, BP, lip [Change_med_yes] [varchar(10)] [yes, no] 2 [] Dietician/Educator Counseling [dietician_edu] [varchar(10)] [yes, no] 3 [] Eye Exam Referral [ophtmology] [varchar(10)] [yes, no] 4 [] Podiatry Referral [podiatry] [varchar(10)] [yes, no] 5 [] Further lab tests today [lab_test] [yes, no] 6 [] Lab tests for next visit specified [other_two] [varchar(10)] [yes, in] months [yes_lab_test] [varchar(10)] 8 [] Other referral/testing, [other_one] [varchar(10)] [s] Other referral/testing,	
1.05	Other visit details	[yes_other_one] [varchar(10)]	
2.	Signature of Res	earch Officer	
2.01	Name:		Signature:

2.02 Date Signed: ____ / ___ / ___ / ____ / ____ / ____ If necessary, update Form G-Eye Exam in Form C (Baseline_Randomization) or Form E (Follow-up 12 monthly_All). Enter this Form I.c into eCRF. Include visit note and any other investigation reports as source documents in participant trial folder.

CARRS Translation Trial; Form Dc – Intermediate Visit_Control v1.2-17JUL2010

FORM X – Serious Adverse Event	v1.2-17JUL2010	Page 1 of 10

*Definition of all the serious adverse events/ and adverse events are included in the Manual of Procedures.

List of Serious Adverse Events

[Please note - SAE has to be recorded using separate event sub-forms and should be submitted to the IRB and sponsors in expedited manner] *Detailed information on reporting timelines are provided in Manual of Procedures.

- 1. Severe hypoglycemia requiring medical attention/hospitalization (a hypoglycemic episode associated with transient central nervous system dysfunction without other apparent cause in which the individual was unable to treat him/herself and had help from another person to administer glucose or glucagon)
- 2. Acute hyperglycemia (e.g. Diabetic Keto Acidosis)
- 3. CVD events: Angina, non-fatal MI / Unstable Angina (ACS), revascularization procedure [angioplasty or CABG], TIA, Stroke (non-fatal), Arrhythmia
- 4. Gangrene or amputation due to diabetes-related peripheral neuropathy and peripheral vascular disease
- 5. Major bleeding (e.g. intracerebral or gastro-intestinal)
- 6. Renal: end-stage renal disease requiring renal replacement therapy (dialysis or transplantation)
- 7. Eyes: severe diabetes-related eye disease (defined as the requirement for retinal photocoagulation or similar treatment and development of diabetes-related blindness in either eye in a participant known not to have this condition at study entry)
- 8. Major infection: requiring hospitalization and/or parenteral antibiotics (UTI, skin infections, soft tissue infections, lower respiratory tract infections/physician-diagnosed pneumonia)
- 9. Inpatient hospitalization or prolongation of existing hospitalization
- 10. Death
- 11. Any other major health conditions/events (important medical event based upon appropriate medical judgment)

List of Adverse Events

[Please Note - Reporting of these events is covered in the regular CRF's / visits]:

- 1. Mild hypoglycemia not requiring medical attention
- 2. Side-effects of medications (e.g. *hepatic dysfunction or myopathy due to statins; dry cough due to ACE-1; negative effects of drugs on biochemical parameters such as hypo- or hyper- kalemia, hyperuricemia; and others per Investigator discretion)*
- 3. PVD: intermittent claudication, rest pain
- 4. Allergic reactions/reactions on basis of drug interactions
- 5. Infection (UTI, skin infections, soft tissue infections, lower respiratory tract infections/physician-diagnosed pneumonia)
- 6. Weight gain

FORM X – Serious Adverse Eventv1.2-17JUL2010Page 2 of 10
Form X - Data saved in dataset as "form_x_patient.csv" and is in long format
Form X: Serious Adverse Event (pg 1 of 2)
Site No. Participant No. Site/Clinic: Participant ID: Participant ID:
[participant_id] [varchar (20)] [participant_initial]
1. Date of onset:
2. Specify event:
[Specific_evering [varchar(20)] [Death (Please complete sub-ORM 1) 1, Transient Ischerinic Attack 2, Ischerinic Stroke 3, Intracerebral hemorrhage (ICH) 4, Stable Angina 5, ACS: Unstable Angina OR Myocardial
Infarction 6, Arrhythmia 7, Gastrointestinal bleeding 8, Eye diseases – Diabetic Retinopathy 9, Infections 10, Renal failure 11, Revascularization / other surgical procedures 12, other
major health condition requiring hospitalization 13]
Death (Please complete subFORM 1)
Transient Ischemic Attack
Ischemic stroke
Intracerebral hemorrhage (ICH)
Stable Angina
CCS: Unstable Angina OR Myocardial Infarction (complete subFORM 2)
Arrhythmia Arrhythmia
Gastrointestinal bleeding
Eye diseases – Diabetic Retinopathy
Renal failure (complete subFORM 3)
Revascularization / other surgical procedures (complete subFORM 4)
☐ Othermajor health condition requiring hospitalization (complete subFORM 5)
3. Prior (pre-enrollment) history of this event? Yes No
[prior_history] [int(11)] [Yes 1, No 2]
4. Was event unexpected? [event_unexpected] [int(1)] [Yes 1, No 2]
5. Related to study intervention?
[study_intervention] [int(11)] [No 1, Unlikely 2, possibly 3, Probably 4, Definitely 5, Unknown 6]
Unlike ly
Possibly Probably
De fin ite ly
If SAE is unexpected (#4) and <i>possibly</i> , <i>probably</i> , <i>or definitely</i> related to study intervention (#5), then immediately call the RCC

Narrative for study intervention related to event: [narrative_study] [text]

FORM X – Serious Adverse Event	v1.2-17JUL2010	Page 3 of 10	
6. Severity:			
[severity] [int(11)] [Mild 1	, Moderate 2, Severe 3, Life	e-threatening/fatal 4]	
Mild			
Moderate Severe			
Lifethreatening/fatal			
7 Man overt aprious (i.e. on SAE)?			
7. Was event serious (i.e. an SAE)? [event_serious] [int(11)]	Yes	□No	
If "Yes," Action Taken:	[165 1, NO 2]		
a. Medical therapy	□Yes	□No	
[medical_therapy] [int(1	1)] [Yes 1, No 2]		
b. Hospitalization (new/prolonged	d) 🗌 Yes	□No	
[hospitalization] [int(11)]			Commented [CR1]: If the response is [Yes 1] specify admission
If "Yes" Admission date:	:		date & discharge date
[admission_date] [date] Discharge date:			
[dischagre_date] [date]			
c. Surgery [surgery] [int(11)] /Yes 1	∐Yes	□No	
d. Transfusion	TYes	□No	
[transfustion] [int(11)] [Yes 1, No 2]		
e. Interruption of study intervention		□No	
[interruption] [int(11)]	Yes 1, No 2]	Permanent	Commented [CR2]: If the response is [Yes 1] specify "Temporary 1" or "Permanent 2"
[interuption_type] [int(1			
8. Outcome of event:			
	1) [Ongoing 1, Resolved	d 2, Resolved with Sequelae 3, Death 4]	
Ongoing			
Resolved, Resolution	ı date: _ / _	/	
[If Resolved 2] →	[resolution_date]	[date]	Commented [CR3]: If the response is [Resolved 2] specify
Resolved with Seque	lae, Resolution date:		resolution date
[resolution_sequel_date]		Sequelae:	
[If Resolved with Sequela	ae 3] → [sequalae]	[varchar(50)]	
Death, Date of death:	: / /		
	te_of_death] [date]	··	
Proximate cause of deat			
	use_of_death] [varcha	ar(50)]	
Person Completing Depart		Date Completed://	
Person Completing Report Last name	First name		
Signature of Investigator:			
Data entered by: initials	Date e	entered:	

FORM X – Serious Adverse Even	t v1.2-17JUL2010	Page 4 of 10
subForm 1: Death (pg 1 of 2)		
Site/Clinic:	Site N Participant ID:	o. Participant No. Participant Initials:
Date of death://(dd/	MMM/yyyy) <mark>[death_date]</mark> [date]	
 Chronology of death: [chronology_death] [int(11)] 	[Not a sudden or unobserved death 1, Su of onset of symptoms or unobserved deat without 2, Sudden unexpected death bet 3, Unobserved death between one and 2 symptoms 4, Unobserved death more the symptoms 5, Unknown 6]	th within 60 minutes of being seen alive veen 1 and 24 hours of onset of symptoms 4 hours of being seen alive without
or unobserved death within Sudden unexpected dea Unobserved death betw symptoms	erved death th within 60 minutes of onset of sy 60 minutes of being seen alive w th beween 1 and 24 hours of onse een one and 24 hours of being see than 24 hours of being seen alive	ithout et of symptoms en alive without
2. Immediate cause of death: [immediate_cause_death] Cardiac tamponade 7, Sudden unexplained of Accidental 12, Pulmonary embolism 13, Non- Infection 18, Non-ICH hemorrhage 19, Other	embolic respiratory disease 14, Renal failu	ac surgery 10, Other cardiovascular 11,
MI Stroke ICH Worsening CHF Arrythmia Cardiac rupture Cardiac tamponade Sudden unexplained card Aortic aneurysm Cardiac surgery Other cardiovascular Accidental Pulmonary embolism Nonembolic respiratory of Renal failure Hepatic falure Malignancy Infection Non/CH hemorrhage Other noncardiovascular	disease	

FORM X – Serious Adverse Event v1.2-17JUL2010 subForm 1: Death (pg 2 of 2) v1.2-17JUL2010

Page 5 of 10

2. Primary underlying cause of death:

[pri_cause_death] [int(11)] [MI 1, Stroke 2, ICH 3, Worsening CHF 4, Arrythmia 5, Cardiac rupture 6, Cardiac tamponade 7, Sudden unexplained cardiovascular 8, Aortic aneurysm 9, Cardiac surgery 10, Other cardiovascular 11, Accidental 12, Pulmonary embolism 13, Non-embolic respiratory disease 14, Renal failure 15, Hepatic failure 16, Malignancy 17, Infection 18, Non-ICH hemorrhage 19, Other non-cardiovascular 20, Unknown 21] MI S troke ICH ICH Worsening CHF Arrythmia Cardiac rupture Cardiac tamponade Sudden unexplained cardiovascular Aortic aneurysm Cardiac surgery Other cardiovascular Accidental Pulmonary embolism Rena failure Hepatic failure 🔲 Malignancy Infection NonICH hemorrhage Other noncardiovascular
 Unknown 3. At onset of fatal event, patient was in: [fatal_event] [int(11)] [Hospital for CHF 1, Hospital for other reason 2, Nursing home 3, Home 4, Rehabilitation center 5, Other 6, Unknown 7] Hospital for CHF Hospital for other reason Nursing home Home Home Rehabilitation center 🔲 Unknown Person Completing Report _ Date Completed: _ _/_ _ _/_ _ _/ Last name First name Signature of Investigator:

Data entered by: | _ _ | initials

Date entered: |__|___|___|

FORM X – Serious Adverse Event	v1.2-17JUL2010	Page 6 of 10				
subFORM 2: Acute Coronary Syndrome Event (MI/Unstable Angina) (pg 1 of 2)						
Site/Clinic:	Site No. Participant ID:	Participant No. Participant Initials:				
Date:/ / (dd/MMM/yyyy)						
Narrative Summary: [narrative_summar	y] [text]					
I. Contraction of the second se						

FROM ECG Reading:

1. Heart rate:	bpm	
[heart_rate] [double]		
2. Rhythm: a. Sinus: [sinus] [int(11)] [Yes 1, No 2] b. Atrial fibrillation: [atrial] [int(11)] [Yes 1, No 2] c. Atrial flutter: [atrial_flutter] [int(11)] [Yes 1, d. Paced: [paced] [int(11)] [Yes 1, No 2]	□Yes □Yes □Yes No 2] □Yes	□No □No □No □No
3. PVC:	□Yes	□No
[pvc] [int(11)] [Yes 1, No 2] 4. LVH: [lvh] [int(11)] [Yes 1, No 2]	□Yes	□No
5. QRS <110 msec:	□Ye s	□No
a. RBBB: [rbbb] [int(11)] [Yes 1, No 2]	□Yes	□No
b. LBBB:	□Yes	□No
[Ibbb] [int(11)] [Yes 1, No 2] c. IVCD: [ivcd] [int(11)] [Yes 1, No 2]	□Yes	□No
6. Q Waves:	□Yes	□No
a. I, aVL:	□Yes	□No
[qwave_a] [int(11)] [Yes 1, No b. II, III, aVF:	□Ye s	□No
[qwave_b] [int(11)] [Yes 1, No c. V^1 - V^4 :	□Ye s	□No
[qwave_c] [int(11)] [Yes 1, No d. V^5 - V^6 : [qwave_d] [int(11)] [Yes 1, No	□Ye s	□No

FORM X – Serious Adverse Event v1.2-17JUL2010	Page 7 of 10
subFORM 2: Acute Coronary Syndrome Event (MI/Unstable	Angina) (pg 2 of 2)
7. Were enzymes drawn? □Yes □No [enzymes] [int(11)] [Yes 1, No 2] If "Yes":	
CK Total Value: [ck_toal_value] [double] Lab upper normal: [ck_lab_upper] [double]	Date drawn: _ / / <mark>[ck_lba_date]</mark>
CK MB Value: %Jnits [ck_mb_value] [int(11)] Lab upper normal: [ck_mb_lab_upper] [double]	Date drawn:/ / [ck_lba_date] <mark>[date]</mark>
Troponin T Units Used (check following): [troponin_t] [int(11)] [Positive 1, Negative 2, Numeric 3] Positive Negative Numeric, Value: [troponin_t_value] Lab upper normal: [troponin_t_upper] [double]	Date drawn: _ / / [date]
Troponin I Units Used (check following): [troponin_i] [int(11)] [troponin_i] [Positive 1, Negative 2, Numeric 3] Positive Negative Numeric, Value: [Intoponin_i value] [troponin_i value] [double] Lab upper normal: [troponin_i_upper]	Date drawn: _ / / [date]
Comments:	
[comment] [text]	
Person Completing Report Date Last name First name	e Completed:/ /
Signature of Investigator:	
Data entered by: initials Date e	entered:

FORM X – Serious Adverse Event	RM X – Serious Adverse Event v1.2-17JUL2010				
subFORM 3: Renal Failure Event (pg 1 of 1)					
Site/Clinic:	Site Participant ID:	No. Participant No. _ Participant Initials:			
Date and Time of Onset of Symptoms: [onset_sym_date]	://;: (2	24 hours clock)			
Complete this form if the participant h	as renal failure requiring o	dialysis.			
1. Was the patient hospitalized? [patient_hospitalize] [int(11)] [ye [if Yes 1] →		□No			
$\Box \longrightarrow \Box Physician's Office$ [hospitalization_type] [int(11)] [Physician's Office]	Physician's Office 1, Emergency Ro	oom 2, Other 3]			
/ / (Date of Hospitalization) [hospitalization_date] [date] 2. Did the participant require any of the fo	Inospitaliza				
	No	Yes			
Hemo dialysis [hemo_dialysis] [int(11)] [Yes 1, I					
Peritoneal dialysis [peritoneal_dialysis] [int(11)] [Ye					
Continuous hemofiltration/ Dialys [conti_dialysis] [int(11)] [Yes 1, N	sis 🗌				
Renal transplant [retal_transplant] [int(11)] [Yes 1,					
3. Serum Creatinine (highest level before		atinine_mg] double]			
4. Date of first dialysis (if applicable): [first_dialysis] [date]	// (dd/MMM/yyyy	/)			
Person Completing Report Last name	Date Cor First name	npleted://			
Signature of Investigator:					
Data entered by: $ $ initials	Date entere	ed:			

FORM X – Serious Adverse Event	v1.2-17JUL2010	Page 9 of 10				
subFORM 4: Surgical Procedures (pg 1 of 1)						
Site/Clinic:	Site No. Participant ID:	Participant No. Participant Initials:				
Person Completing Report	Date Complet	ed:/ /				
Surgical Intervention Procedures						
1. Procedure [p_procedure] [varchar(50)]						
 Date of procedure [p_procedure_date] [date] 	_ / _ _ _ / _ _ _ d d M M M y y y					
Last name	First name					
Signature of Investigator:						
Data entered by: $ $ initials	Date entered: _					
subFORM 5: Hospitalization (pg 1 of	<u>1)</u>					
Site/Clinic:	Site No. Participant ID:	Participant No. Participant Initials:				
1. Admission date	/ / d d M M M y y y					
[hospital_addm_date] [date] 2. Reason for Hospitalization: [hospitaliza_reason] [int(11)] [S [Angina 3, [Perpheral Vascular disease [Arrhythmia 8, [Jangrene or amputation [severe diabetesrelated eye 12, [Major in []Death 15, []Any other major health condition []Acute hyperglycemia (e.g. Diabetest []Acute hyperglycemia (e.g. Diabetest []Arngina []Peripheral Vascular disease []Revascularization procedure [ar []TIA []Stroke []Arrhythmia []Gangrene or amputation []Major bleeding (e.g. intracerebratest []Renal failure []severe diabetes-related eye []Major infections []npatient hospitalization or prolo []Death []Any other major health condition	evere hypoglycemia 1, [Acute hypergl 4, [Revascularization procedure [angio, 9, [Jajor bleeding (e.g. intracerebal or flections13, [Inpatient hospitalization or p ions/events 16] etic Keto Acidosis) ngioplasty or CABG], al or gastro-intestinal) ngation of existing hospitalization	vcemia (e.g. Diabetic Keto Acidosis) 2, obasty or CABGJ 5, DTA 6, Ditroke 7, gastro-intestinal) 10, Renal failure 11,				

FORM X – Serious Adverse Event	v1.2-17JUL2010	Page 10 of 10
3. Still in hospital at study completion [still_in_hospital] [int(11)] [Yes 1, No 2] Yes No		
Discharge date		
[hospital_discharge_dat	e] [date]	
/ /		
d d MMM y	уууу	
Person Completing Report Last name [last_name] [varchar(20)]	First name [frist_name] [varchar(20)]	
Date Completed:// [date_completed] [date] Signature of Investigator:		
Data entered by: initials	Date entered: I	_
[data_entry_by] [varchar(20)]	[data entered] [d	
		atej

 Place See I Store in pat 	tes dd/MMM/yyyy (e.g. 31/DEC/20 e cross [X] in the appropriate boxes. Form Completion Notes, for definitio copies of available source docume tient's trial folder	Write in fields c ins and explanat nts (SD), where	learly. [d tions In indicated, D	lata_er iitials _ ATE e	try by: htry_by] [varchar(100)] ntered: / / htered] [date]		
CARRS	I C – Baseline Randomizatior S Translation Trial story – Data saved in "patient_f	Dat		Pa [pa	eening ID: S rticipant Initials: inticipant_id] [varchar(20)] / / / [date_of_visit] [date]		
		Year of Diagnosis					
1.01	Type 2 Diabetes [h_type2_diabetes_year] [varchar(6)]		1[] Unknown [h_is_type2_diabetes [int] [Unknown 1]]			Commented [CR1]: If the response is [Unknown] data is saved as '1'
1.02	Hypertension [h_hypertension_year] [varchar(6)]		1[] Unknown [h_is_hypertension] [int] [Unknown 1, Not ap	plicable	2[] Not applicable		Commented [CR2]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'
1.03	Hyperlipidemia [h_hyperlipidemia_year] [varchar(6)]		1[] Unknown [h_is_hyperlipidemia] [int] [Unknown 1, Not ap		2[] Not applicable		Commented [CR3]: If the response is [Unknown] or [Not applicable] data is saved as '1' or '-1'
1.04	How first diagnosed with diabet [h_first_diagnosed_with_diabete [Testing after symptoms emerged 1, At routine check-up, no symptoms 2, Active screening 3, Diagnosed during pregnancy 4, Other 5]		impotence, pruritis, v	, polyph vision p :-up, n	agia, weight loss, low energy, roblems, giddiness, aches/pains) O symptoms (urine test, (testing by		
		Diabetes?		Kidı	ney failure?		
	Number of children with [h_no_children_with_diabetes] [int(11)] [h_no_children_with_kidney_fail ure] [int(11)]	-	nown, N/A <mark>I_with_diabetes_fail]</mark>		[] Unknown, N/A [is_chid_with_kidney_fail] [int] [-1]		Commented [CR5]: If the response is [Unknown, N/A] data is saved as '-1' Commented [CR4]: If the response is [Unknown, N/A] data is saved as '-1'
1.06	Number of brothers/sisters with [h_no_brother_sister_with_diabe		nown, N/A		[] Unknown, N/A	K	Commented [CR7]: If the response is [Unknown, N/A] data is saved as '-1'

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

[is_brosis_with_diabetes] [int] [-1]

_

_

[Int(11)] [h_no_brother_sister_with_kidne y_failure] [int(11)]

Page 1 of 28

[is_brosis_with_kidney_fail [int] [-1]

Commented [CR6]: If the response is [Unknown, N/A] data is saved as '-1'

1.07	Number of parents with [h_no_parents_with_diabetes] [int(11)] [h_no_parents_with_kidney_failu re] [int(11)]	 [] Unknown [is_parents_with_diabetes] [int] [-1]	 [].Unknown [is_parents_with_kidney_fa il] [int] [-1]	Commented [CR8]: If the response is [Unknown] data is saved as '-1' Commented [CR9]: If the response is [Unknown] data is saved as '-1'
1.08	Number of grandparents with [h_no_grandparents_with_diabet es] [int(11)] [h_no_grandparents_with_kidne y_failure] [int(11)]	 [] Unknown [is_granparent_with_diabetes] [int] [-1]	 [] Unknown [is_granparent_with_kidne y_fail] [int] [-1]	Commented [CR10]: If the response is [Unknown] data is saved as '-1' Commented [CR11]: If the response is [Unknown] data is saved as '-1'

1.09	Is there a history of <u>HEART DISEASE or HEART ATTACK</u> in a brother, sister, or parent? <i>If YES, was it at an early age?</i> (Early age = Before Age 55 for father/brother; 65 for mother/sister) [h heart attack brother sister parents] [int(11)]	1[] Yes, at an EARLY AGE 2[] Yes, age unknown 3[] No 4[] Unknown
	[Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]	
1.10	Is there a history of <u>STROKE</u> in a brother, sister, or parent? If YES, was it at an early age? (Early age = Before Age 55 for father/brother; 65 for mother/sister) [h_stroke_brother_sister_parents] [int(11)] [Yes, at an EARLY AGE 1, Yes, age unknown 2, No 3, Unknown 4]	1[] Yes, at an EARLY AGE 2[] Yes, age unknown 3[] No 4[] Unknown

	Cardiovascular	no/ unsure	yes		
1.11	ACS: Myocardial Infarction or Unstable Angina [h_cardiovascular_acs] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, list year(s): [h_cardiovascular_acs_year] [varchar(20)]	Commented [CR12]: If the response is [yes 1] for Q.no.1.11 to 1.16 - specify the year
1.12	Angioplasty (PCI) /Open-heart surgery (CABG) [h_cardiovascular_pci_cabg] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, list year(s): [h_cardiovascular_pci_cabg_year] [varchar(20)]	
1.13	Chronic Stable Angina [h_cardiovascular_chronic_sa] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, since (year): [h_cardiovascular_chronic_sa_year] [varchar(20)]	
1.14	Stroke (Ischemic or Hemorrhagic) or TIA [h_cardiovascular_stroke_tia] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, list year(s): [h_cardiovascular_stroke_tia_year] [varchar(20)]	
1.15	Arrhythmia (requiring medical intervention) [h_cardiovascular_arrtythmia] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, since (year): [h_cardiovascular_arrtythmia_year] [varchar(20)]	
1.16	Heart Failure	[]	[]	If yes, since (year):	
				B	

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 2 of 28

·		7			
	h_cardiovascular_heart_attack] [int(11)] Yes 1, no/unsure 2,]		ardiova char(20	ascular_heart_attack_year]	
				"	
		no/			
	Peripheral Vascular/Neuropathy	unsure	yes		
1.17	PVD (Intermittent claudication/ rest pain in legs) [h_peripheral_vascular_pvd] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, since (year): [h_peripheral_vascular_pvd_year] [varchar(20)]	Commented [CR13]: If the response is [yes 1] for Q.no.1.17, 1.18 - specify the year & for Q.no.1.19 response is [yes 1] - specify number of times
1.18	Peripheral revascularization (angioplasty/ surgery) [h_peripheral_surgery] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, list year(s): [h_peripheral_surgery_year] [varchar(20)]	
1.19	Chronic leg/foot ulcer (6 weeks or more) [h_peripheral_foot_ulcer] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, number of times: [h_peripheral_foot_ulcer_year] [varchar(20)]	
	Eyes	<u> </u>			
1.20	Blindness in either eye thought to be due to diabetes [h_eyes_blindbess] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, []R []L []both [h_eyes_is_blindbess] [varchar(20)] [R right, L left, B both]	Commented [CR14]: If the response is [yes 1] for Q.no.1.20 to 1.22 - specify the direction [right, left or both
1.21	Cataract [h_eyes_cataract] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, []R []L []both [h_eyes_is_cataract] [varchar(20)] [R right, L left, B both]	
1.22	Cataract Surgery [h_eyes_cataract_surgery] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, []R []L []both [h_eyes_is_cataract_surgery] [varchar(20)] [<i>R right, L left, B both</i>]	
1.23	Glaucoma	[]	[]		
	[h_eyes_glaucoma] [int(11)] [Yes 1, no/unsure 2,]				
1.24	Macular Edema [h_eyes_macular_edema] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.25	Diabetic Retinopathy [h_eyes_diabetic_retinopathy] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.26	Laser photocoagulation therapy [h_eyes_laser_therapy] [int(11)] [Yes 1, no/unsure 2,]	[]	[]	If yes, number of <mark>times</mark> :	Commented [CR15]: We can ignore this because Variable not found in both front-end & back-end
1.27	Other therapy [h_eyes_other_therapy] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
	OTHER				
1.28	Neuropathy – hands/feet [h_other_neuropathy_hands_feet] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.29	Neuropathy – sexual (erectile dysfunction) [h_other_neuropathy_sexual] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.30	Nephropathy (protein in urine)	[]	[]		

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 3 of 28

	[h_other_neuropathy_urine] [int(11)] [Yes 1, no/unsure 2,]				
1.31	Chronic urinary tract infection (2+ in 6 months) [h_other_chronic_urinary] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.32	Past tuberculosis [h_other_past_tuberculosis] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.33	Asthma [h_other_asthma] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.34	COPD (Chronic Bronchitis, Emphysema) [h_other_copd] [int(11)] [Yes 1, no/unsure 2.]	[]	[]		
1.35	Liver disease [h_other_liver_disease] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.36	Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.37	Hip Fracture/Replacement [h_other_hip_facture] [int(11)] [Yes 1, no/unsure 2,]	[]	[]		
1.38	Depression [h_other_depression] [int(11)] [yes 1, no/unsure 2,]	[]	[]		
1.39	Major hypoglycemia episodes (hospitalization or emergency room visit) [h_other_major_hypoglycemia] [int(11)] [Yes 1, no/unsure 2.]	[]	[]	If yes, number of <mark>times</mark> : [h_other_is_major_hypoglycemia] [int(11)]	Commented [CR16]: If the response is [yes 1] for Q.no.1.39 & 1.40 – specify number of times
1.40	Other hospitalization for diabetes [h_other_hospitalization] [int(11)] [Yes 1, no/unsure 2]	[]	[]	If yes, number of times: [h_other_is_hospitalization] [int(11)]	
1.41	Other conditions (current or past) which have require [h_other_conditions] [varchar(200)]	ed medi	cations	or surgical intervention:	

2. ECG & Eye Exam

May use results from past 1 month. Retain copies of ECG and eye exam results as source documents.

ECG: May use results from past 1 month. Otherwise, complete test today.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 4 of 28

2.01	ECG Date:// [s_ecg	_date] [date]	
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] [Yes 1, No 2]	1[]Y	2[]N
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] [Yes 1, No 2]	1[]Y	2[]N
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] [Yes 1, No 2]	1[]Y	2[]N
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] [Yes 1, No 2]	1[] Y	2[]N

Commented [CR17]: ECG date should be within one month of Form B Date of visit

EYE EXAM: May use results from past 1 month.

[] Attach Form G-Eye Exam to end of this Form C – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 5 of 28

		Right Foot		Left Foot		
2.04	A manufaction			[]N/A		-
3.01	Amputation [fe_amputation_right_foot] [int(11)] [fe_amputation_left_foot] [int(11)] [IN/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5, below knee 6, above knee 7]	[]N/A []toe []ray (metatarsal) []forefoot []foot []below knee []above knee	[] toe [] toe [] ray (metatarsal) [] ray [] forefoot [] fore [] foot [] foot [] below knee [] below [] above knee [] above		e	
3.02	Appearance [fe_appearance_right_foot_normal] [int(11)] [normal 1, abnormal 2] [fe_appearance_left_foot_normal] [int(11)] [normal 1, abnormal 2] [fe_appearance_right_foot_deformities] [int(11)] [1] [fe_appearance_right_foot_dystrophic] [int(11)] [2] [fe_appearance_right_foot_callus] [int(11)] [3] [fe_appearance_right_foot_unceration] [int(11)] [4] [fe_appearance_right_foot_infection] [int(11)] [5] [fe_appearance_right_foot_discoloration] [int(11)] [6] [fe_appearance_right_foot_other] [int(11)] [7] [fe_appearance_right_foot_other_details] [varchar(200)] [other specify]	1[] normal 2[] abnormal, che that apply: 1[] deformities 2[] dystrophic na skin/fissure 3[] callus 4[] ulceration 5[] infection 6[] discoloration 7[] other:	ils; dry	1[] normal 2[] abnorma that apply: 1[] deforn 2[] dystro skin/fissure 3[] callus 4[] ulcera 5[] infecti 6[] discol 7[]other:	nities phic nails; dry tion ion	Commented [CR18]: If the response is [abnormal 2] specify below mentioned options 1 to 7 (check all that apply) for right foot & left foot [fe_appearance_left_foot_deformities] [int(11)] [1] [fe_appearance_left_foot_dystrophic] [int(11)] [2] [fe_appearance_left_foot_unceration] [int(11)] [3] [fe_appearance_left_foot_unceration] [int(11)] [4] [fe_appearance_left_foot_unceration] [int(11)] [5] [fe_appearance_left_foot_therologication] [int(11)] [6] [fe_appearance_left_foot_therol_details] [varchar(200)] [other specify]
3.03	Posterior tibial pulse [fe_posterior_right_foot] [int(11)] [Yes 1, No 2] [fe_posterior_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[] N	
3.04	Doraslis pedis pulse [fe_doraslis_right_foot] [int(11)] [Yes 1, No 2] [fe_doraslis_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[]N	
3.05	Pre-tibial EDEMA today [fe_pre_tibial_edema_right_foot] [int(11)] [fe_pre_tibial_edema_left_foot] [int(11)] [None 0, up to ankle 1,between ankle & mid-calf 2, between mid-calf & knee 3]	[] none [] up to ankle [] between ankle & mid- calf [] between mid-calf & knee] none] up to ankle] between ankle & mid-calf] between mid-calf & knee 		
3.06	Ankle Reflex [fe_ankle_relax_right_foot] [int(11)] [Yes 1, No 2] [fe_ankle_relax_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[]N	
3.07	Knee Reflex [fe_knee_reflax_right_foot] [int(11)] [Yes 1, No 2] [fe_knee_reflax_left_foot] [int(11)] [Yes 1, No 2]	1[] Y	2[] N	1[] Y	2[] N	
3.08	Vibration, tuning fork (perception at great toe) [fe_vibration_right_foot] [int(11)] [fe_vibration_left_foot] [int(11)] [present (>10 sec) 1, reduced (<10 sec) 2, absent 3]	[] present (≥10 se [] reduced (<10 se [] absent		[] present (a [] reduced ([] absent	,	
0400	S Translation Trial: Form C – Baseline Randomization					

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

3.09	10g Monofilament (number applications detected) [fe_monofilament_right_foot] [int(11)] [fe_monofilament_left_foot] [int(11)] [present (≥8) 1, reduced (1-7) 2, absent 3]	[] present (≥8) [] reduced (1-7) [] absent	[] present (≥8) [] reduced (1-7) [] absent	
3.10	Based on above the participant has:			
	Deformities	1[]Yes	2[] No	
	[fe_participant_has] [varchar(20)]			Commented
	[Yes 1, No -1]			responses and & re naming th
	Foot ulceration/infection [Yes 2, No -2]	1[] Yes	2[] No	
	PVD [Yes 3, No -3]	1[] Yes	2[] No	
	Neuropathy [Yes 4, No -4]	1[] Yes	2[] No	

ed [CR19]: For Q.no.3.10 to 3.14 has multiple d data stored in this column as string so we are splitting g the categories as [1,-1, 2,-2, 3,-3, 4,-4]

Heart Failure Exam 4.

	Have you experienced any of the foll	owing since yo	ur last exam?	
	swelling of your feet, ankles or legs	1[] <mark>Yes</mark> →	1[] new or worsened	Commented [CR20]: If the response is [yes 1] for Q.no.4.01 to
4.01	[hf_swelling_feet] [int(11)]	2[] No	2[] unchanged or improved	4.03 – specify '1' or '0' [new or worsened 1, unchanged or improved 0]
1.01	[Yes 1, No 2, N/A 3] [if Yes 1] →		[hf_is_swelling_feet_new]	[new of worsened 1, anomalged of improved of
			[new or worsened 1, unchanged or improved 0]	
	shortness of breath while lying,	1[]Yes →	1[] new or worsened	
4.02	sitting, or with minimal exertion	2[] No	2[] unchanged or improved	
4.02	[hf_shortness_of_breath] [int(11)]		[hf_is_shortness_of_breath_new]	
	[Yes 1, No 2, N/A 3] [if Yes 1] →		[new or worsened 1, unchanged or improved 0]	
	need to pass urine two or more times	1[]Yes →	1[] new or worsened	
4.03	per night	2[] No	2[] unchanged or improved	
4.03	[hf_pass_urine] [int(11)]		[hf_is_pass_urine_new]	
	[Yes 1, No 2, N/A 3] [if Yes 1] ->		[new or worsened 1, unchanged or improved 0]	

If any	If any 4.01-4.03 is YES, complete below.								
Ches	t Auscultation								
4.04	Lungs [hf_chest_ausculation_lungs] [int(11)] [no rales 1, basilar rales only 2, more than basilar 3]	1[] no rales 2[] basilar rales only 3[] more than basilar							
4.05	Heart [hf_chest_ausculation_heart] [int(11)] [normal 1, abnormal 3rd heart sound present 2]	1[] normal 2[] abnormal, 3 rd heart sound present							
4.06	Heart Failure evident [hf_chest_ausculation_heart_failure] [int(11)] [Yes 1, No 2]	1[] Yes, grade: 2[] No [heart_failure_grade] [varchar(45)]							

Commented [CR21]: If the response is [yes 1] for Q.no.4.06 – specify grade

Neurological Exam 5.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 7 of 28

	Here and the first state of the	- 11					
	Have you experienced any of the fo			[
	Muscle weakness		[] <mark>Yes_→</mark>	1[] new o			
5.01	[ne_muscles_weakness] [int(11)] [Yes 1, No 2, N/A 3] [if Yes 1] \rightarrow	2	[] No	2[] unchanged or improved [ne_is_muscles_weakness_new] [int(11)			ewl [int(11)]
				-		1, unchanged or	
	Difficulty in speech	1	[]Yes →	1[] new o	r wo	orsened	
5.02	[ne_difficulty_in_speech] [int(11)]	2	[] No	2[] uncha	inge	d or improved	
	[Yes 1, No 2, N/A 3] [if Yes 1] →			-		n_speech_new	
	Loss of consciousness	1	[]Yes		eneu	1, unchanged or	improved oj
5.03	[ne_loss_consciousness] [int(11)]] No				
	[Yes 1, No 2, N/A 3]						
If any	5.01-5.03 is YES, complete below.						
	Muscles		Right			Left	
	ARMS-Tone						
5.04	[ne_arms_tone_right] [int(11)]		[] normal	[] flaccio	ł	[] normal	[] flaccid
	[ne_arms_tone_left] [int(11)] [normal 1, flaccid 2, rigid/spastic 3]		[] rigid/spa	SUC		[] rigid/spast	IC
	ARMS-Strength						
5.05	[ne_arms_strengt_right] [int(11)]		7 1	114.0		5 1 a a a a a	5 1 de Celt
5.05	[ne_arms_strengt_left] [int(11)]	[] normal	[] deficit		[] normal [] deficit		
	[normal 1, deficit 2]						
	LEGS-Tone						
5.06	[ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)]	[] normal [] flaccid [] rigid/spastic			[] normal [] rigid/spast	[] flaccid	
	[normal 1, flaccid 2, rigid/spastic 3]		[]			[]9	
	LEGS-Strength						
5.07	[ne_legs_strength_right] [int(11)]		[] normal	[]defic	cit	[]normal	[] deficit
	[ne_legs_strength_left] [int(11)]		[]	[]		[]	[]
	[normal 1, deficit 2]						
	Reflexes		Right			Left	
	Biceps						
5.08	[ne_reflexes_biceps_right] [int(11)]		[]present	[]abse	nt	[]present	[]absent
	[ne_reflexes_biceps_left] [int(11)] [present 1, absent 2]						
	Triceps						
5.09	[ne_reflexes_triceps_right] [int(11)]			[]ahaa	nt	[]procont	
5.09	[ne_reflexes_triceps_left] [int(11)]		[]present	[]absent		[]present []absent	
L	[present 1, absent 2]						
5.10	[ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)]		[]present	[]abse	nt	[]present	[]absent
	[present 1, absent 2]						
	Ankle						
5.11	[ne_reflexes_ankle_right] [int(11)]		[]present	[]abse	nt	[]present	[]absent
	[ne_reflexes_ankle_left] [int(11)] [present 1, absent 2]						
L	Iprocent 1, absont 2j		I				
5.12] Yes			2[] No	
	[ne_old_deficit] [int(11)]						
	[Yes 1, No 2]						

Commented [CR22]: If the response is [yes 1] for Q.no.5.01 & 5.02 – specify '1' or '0' [new or worsened 1, unchanged or improved 0]

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 8 of 28

6. MEDICATIONS and MANAGEMENT

6.01		[varchar(20)] [Yes 1, No]No []Unknown	[]Yes, specify:	
	[drug_allergies]					Commented [CR23]: If the response is [Y name
6.02	MEDICATIONS	– Data is saved in "me	dication_mgt.cs	v" file and is in long f	ormat	
Below,	list all medications	s that the participant is p	presently taking or	a regular basis (prior i	o randomization).	
^For (1) Insulin, (2) OHA	As, and (3) Blood press	sure <u>MIXED medi</u>	cations, describe all o	constituents	
separa	tely under "Gene	ric Name" and "Single	e Dose"			
		^List ALL cons Insulin, OHAs,	tituents for BP meds			
Туре	Brand Name [name]	Generic Name	Single Dose	Frequency	Total daily dose	
	[varchar(200)]	[generic_name] [varchar(200)]	[single_dose] [double]	[frequency] [double]	[total_daily_dose] [double]	
nsulin						
OHAs						
3P						
Notio						
Statin						

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 9 of 28

Туре	Brand Name	Generic Name	Single Dose	Frequency	Total daily dose
Other					

6.03		Management of diabetes in last 6 months	
		[dibetes_mgt] [varchar(50)]	[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1
	[]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)	Biguanide (Metformin) 2
	[]	Biguanide (Metformin)	Thazolidineodione (Pioglitazone) 3
	[]	Thazolidineodione (Pioglitazone)	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)-
	[]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)	Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
	[]	Glinide (Nateglinide, Repaglinide, Mitiglinide)	Lispro, Aspart, Glulisine insulins (rapid-acting) 6
	[]	Lispro, Aspart, Glulisine insulins (rapid-acting)	Regular Insulins (short-acting) 7 NPH or Lente Insulins (intermediate-acting) 8
	[]	Regular Insulins (short-acting)	Glargine or Determir Insulins (very long-acting) 9
	[]	NPH or Lente Insulins (intermediate-acting)	Other diabetic treatment 10
	[]	Glargine or Determir Insulins (very long-acting)	Dietician or Educator referral 11
	[]	Other diabetic treatment	Weight control or exercise program 12
	[]	Dietician or Educator referral	Home blood glucose monitoring 13
	[]	Weight control or exercise program	
	[]	Home blood glucose monitoring	
6.04		Other medications	
		[other_dibetes_mgt] [varchar(100)]	
	[]	Thaizide or thiazide-like diuretic	
	[]	Other diuretic	

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 10 of 28

[]	ACE inhibitor	Thaizide or thiazide-like diuretic 1
[]	Angiotensin 2 receptor antagonist (ARB)	Other diuretic 2
[]	Beta-blocker	ACE inhibitor 3
[]	Calcium channel blocker (CCB)	Angiotensin 2 receptor antagonist (ARB) 4
[]	Other antihypertensive agent	Beta-blocker 5
[]	Statin	Calcium channel blocker (CCB) 6 Other antihypertensive agent 7
[]	Other cholesterol lowering drug	Statin 8
[]	Aspirin	Other cholesterol lowering drug 9
[]	Other anti-platelet agent	Aspirin 10
[]	Oral anticoagulant	Other anti-platelet agent 11
[]	Nitrates (NOT sublingual)	Oral anticoagulant 12
		Nitrates (NOT sublingual) 13 Hormone replacement therapy 14
[]	Hormone replacement therapy	Thyroid Agents 15
[]	Thyroid Agents	Oral/inhaled steroids 16
[]	Oral/inhaled steroids	Oral asthma drugs (exclude steroids) 17
[]	Oral asthma drugs (exclude steroids)	Antidepressant 18
[]	Antidepressant	Anti-neuropathy medications (gabapentin, pregabalin,
[]	Anti-neuropathy medications (gabapentin, pregabalin, amatryptiline)	amatryptiline) 19
[]	Erectile Dysfunction drug	Erectile Dysfunction drug 20 Herbal/alternative medicine 21
[]	Herbal/alternative medicine	Vitamins/nutritional supplements 22
[]	Vitamins/nutritional supplements	Other, not listed above 23
[]	Other, not listed above	

7. Randomization

7.01	[]Y	[]N	Completed all of Form C, Part 1 above. If NO, complete now.
7.02	[]Y	[]N	Reviewed Forms and Eligibility with Investigator or Co-Investigator. If NO, review now.
7.03	[]Y	[]N	Patient agrees to continue with the trial If NO, stop here and complete patient status in PARTICIPANT LOG.

If YES for ALL 7.01-7.03, continue to Randomization:

- 1. Information from Participant Log will be required to complete the Randomization.
- Select Randomization option on website <u>www.coe-carrs.phfi.in</u> (CARRS Translation Trial > Randomization) and enter requested data
 - a. Screening Officer Name
 - b. Screening ID (do not include 'S' only numbers)
 - c. Confirm Screening ID (do not include 'S' only numbers)
 - d. Date of Birth (dd/MMM/yyyy)
 - e. Confirm Date of Birth (dd/MMM/yyyy)
 - f. Was the eligibility of the participants to both treatment arms confirmed by investigator?
 - g. Has the participant met all eligibility criteria?

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 11 of 28

- h. Has the participant met any of the exclusion criteria?
- i. Did the participant sign informed consent?

OR IF INTERNET ACCESS NOT POSSIBLE:

Γ

3. Telephone +011 2685-0117/18 and ask for CARRS Translation Trial Randomization

7.04 Result of Randomization: - enter information below & attach print-out from randomization page:

	PARTICIPANT ID:	USE THIS ID in future CRF and eCRF	
[treatr	Allocation: [] Control Group ment_group] [varchar (20)], [INTERVENTION, C	[] Intervention Group	
เตอต	nent_groupj [varchar (20)], [intervention, c	UNI ROLJ	
8.	Signature of Study Physician		
8.01	Name:	Signature:	
8.02	Date Signed: / / / / /	_	
8.03	Complete Participant Log for this patient		
8.04	Check one of the following:		
	$\begin{bmatrix} 1 \text{ Control Group Participant} \rightarrow \text{ send to} \end{bmatrix}$	Research Officer to complete Form C Part 2 (below)	
		nd to Care Coordinator to complete Form C Part 2 (below)	
PART	2: complete by CARE COORDINATOR or	RESEARCH OFFICER	
9.	Demographics		
	•		
9.01	Marital Status	[Single 1, Married 2, Widow/Widower 3, Separated/Divorced 4]	
	[matrial_status] [int], 1[] Single	3[] Widow/Widower	
	2[] Married	4[] Separated/Divorced	
9.02	Occupation		
	[occupation] [int]		
	business owner, staff manager, mid-level farmer, tea	cher, class 1 IAS/services officer, lawyer, 2 Trained, clerical, medium cher, 3 Skilled manual laborer, small business owner, small farmer, 4 Semi- / driver, army jawan, carpenter, fitter, 5 Unskilled manual laborer, landless moloved, 11 Otherl	
		niversity teacher, class 1 IAS/services officer, lawyer	
	2[] Trained, clerical, medium business ow	ner, staff manager, mid-level farmer, teacher	
	3[] Skilled manual laborer, small business		
		landowner, rickshaw driver, army jawan, carpenter, fitter	
	5[] Unskilled manual laborer, landless lab	orer	
	6[] Homemaker		
	8[] Student 9[] Retired		
	10[] Unemployed		
	11[] Other		
0.00		k 181/A	
9.03	Days per week that you work: [days_per_week_work] [int (1)]	[] N/A [days_per_week_work_na] [int] [(N/A) 1]	Commented [CR24]: If as '1'

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 12 of 28

ponse is [N/A] data is saved

	Hours per day that you work:	[] N/A	Commented [CR25]: If the response is [N/A] data is saved
	[hours_per_day_work] [int(2)]	[hours_per_day_work_na] [int] [(N/A_1)]	as '1'
9.04	TOTAL number of household members:		
	[no_household] [int(2)]		
9.05	Number of children in household:		
	[no_children] [int(2)]		
9.06	Number of adults in household:		
	[no_adult] [int(2)]		
9.07	Number of adults in household earning:		
	[no_adult_earning] [int(2)]		
9.08	During last 12 months, HOUSEHOLD monthly income:		
	[household_income] [int] [<3,000 1, 3,000-10,000 2, 10,000-20,000	0 3, 20,001-30,000 4, 30,001-40,000	
	5, 40,001-50,000 6, >50,000 7, Unknow	n/ Refuse 8]	
	1[]<3,000 4[]20,001-30,000	7[]>50,000	
	2[] 3,000-10,000 5[] 30,001-40,000	8[] Unknown/ Refuse	
	3[] 10,000-20,000 6[] 40,001-50,000		
	During last 12 months, INDIVIDUAL monthly income:	Rupees	
	[individual_income] [int] [<3,000 1, 3,000-10,000 2, 10,000-20,000 3	3, 20,001-30,000 4, 30,001-40,000	
	5, 40,001-50,000 6, >50,000 7, Unknown/ F	Refuse 8]	
	1[]<3,000 4[]20,001-30,000	7[]>50,000	
	2[] 3,000-10,000 5[] 30,001-40,000	8[] Unknown/ Refuse	
	3[] 10,000-20,000 6[] 40,001-50,000		
	3[]10,000-20,000 0[]40,001-30,000		
9.09	Highest Level of Education of Participant:		
3.03	[highest_education] [int] [1 Professional degree/post graduate, 2 Gra	aduato (RA, RSo, RCom, Diploma)	
	3 Secondary School, Standard, 4 Primary Sch		
	5 Literate, no formal education, 6 Illiterate, 7 U		
	1[] Professional degree/post graduate		
	2[] Graduate (BA, BSc, BCom, Diploma)		
	3[] Secondary School, Standard:		
	4[] Primary School (up to class 5), Standard:		
	5[] Literate, no formal education		
	6[] Illiterate		
	7[] Unknown		
9.10	Mother Tongue (Ethnic Origin):	i 5 Kennede - C.Kenhmiri - 7 Meithili	
	[mother_tongue] [int (2)] [1 Assamese, 2 Bengali, 3 Gujarati, 4 Hind 8 Malavalam, 9 Marathi, 10 Puniabi, 11 Sin	dhi, 12 Telugu, 13 Tamil, 14 Urdu, 15 other, specify,	
	16 Unknown]		
	1[] Assamese 10	0[] Punjabi	
		1[] Sindhi	
		2[]Telugu	
	•••	3[]Tamil	
		4[] Urdu	
		5[] Other, specify:	
		mother_tongue_other] [varchar(50)] 6[] Unknown	
	9[] Marathi		
	ə[] marallı		
9.11	Knows English language (check all that apply OR none):		
0.11	[english_language] [int(10)] [(understand 1, speak 2, read/write 3, I	None 4)1	
	1[] understand	····· ·//	
CARRS	Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010	Page 13 of 28	

- 2[] speak 4[] none
- 3[] read/write
- 9.12 Religion:

[religion] [int] [1 Hindu, 2 Muslim, 3 Sikh, 4 Christian, 5 Jain, 6 Buddhism, 7 No religion, 8 other, specify, 9 unknown/refuse]

- 1[] Hindu
- 2[] Muslim
- 3[] Sikh
- 4[] Christian
- 5[] Jain

- [religion_other] [varchar(50)] 9[] unknown/refuse

6[] Buddhism

7[] No religion

8[] other, specify: _

10. Lifestyle - Data is saved in "patient_life_style.csv" and is wide format

10.05	Diet (weekday/ routine day)	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6	
	Meal Time (approximate)	[meal1_ampm] [varchar(6)] [AM or PM]	[meal2_ampm] [varchar(6)] [AM or PM]	[meal3_ampm] [varchar(6)] [AM or PM]	[meal4_ampm] [varchar(6)] [AM or PM]	[meal5_ampm] [varchar(6)] [AM or PM]	[meal6_ampm] [varchar(6)] [AM or PM]	
		_: amPm	Commented [CR26]: Should specify [AM or PM]					
		[meal1_time] [varchar(5)]	[meal2_time] [varchar(5)]	[<mark>meal3_time]</mark> [varchar(5)]	[meal4_time] [varchar(5)]	[meal5_time] [varchar(5)]	[meal6_time] [varchar(5)]	
		 '	·'	+	+'	'		Commented [CR27]: Should specify time of the meal
	Type B=breakfast, L=lunch.	[meal1_type] [varchar(6)]	[meal2_type] [varchar(6)]	[meal3_type] [varchar(6)]	[meal4_type] [varchar(6)]	[meal5_type] [varchar(6)]	[meal6_type] [varchar(6)]	Commented [CR28]: Should specify type of meal i.e.,
	D=dinner, S=snack							B=breakfast, L=lunch, D=dinner, S=snack

10.02 Who decides the meal menu in the household? (check one) [household_meal_menu] [varchar(10)] [(Myself 1, other 2, shared (myself and other) 3)]

[] other (i.e. spouse, relative, hired cook) [] Shared (myself and other) [] Myself

10.03 Who cooks the food in the household? (check one) [household_cook_food] [varchar(10)] [(Myself 1, other 2, shared (myself and other) 3)]

[] other (i.e. spouse, relative, hired cook) [] Myself [] Shared (myself and other)

10.04	Physical Activity (in leisure time) in average			
	week	Days per week	Total time per day	
			Hour(s)	Minutes
	Vigorous	[<mark>pa_vigorous_days_per_week</mark>]	[<mark>pa_vigorous_total_hr]</mark>	[pa_vigorous_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Moderate	[pa_moderate_days_per_week]	[pa_moderate_total_hr]	[pa_moderate_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Mild (Walking)	[<mark>pa_walking_days_per_week</mark>]	[pa_walking_total_hr]	[pa_walking_total_min]
		[int(11)]	[int(11)]	[int(11)]

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 14 of 28

.05	Ever use tobacco ever_use_tobacco] [int(11)]	[Yes=1; No=2]	[] Y Continue be [] N Skip to 10.0	
	Current regular use Y N	Past regular use Y N	Number of years used	Current/past Average Quantity per day
Cigarette	[][] [cigarette_regular_use] [int(11)] [Yes=1; No=2]	[] [] [cigarette_past_use] [int(11)] [Yes=1; No=2]	[cigarette_no_of_year] [int(11)]	[cigarette_qty_per _day] [int(11)]
Beedi	[] [] [beedi_regular_use] [int(11)] [Yes=1; No=2]	[] [] [beedi_past_use] [int(11)] [Yes=1; No=2]	[beedi_no_of_year] [int(11)]	[beedi_qty_per_da y] [int(11)]
Cigar/Pip e	[] [] [cigar_pipe_regular_use] [int(11)] [Yes=1; No=2]	[] [] [cigar_pipe_past_use] [int(11)] [Yes=1; No=2]	[cigar_pipe_no_of_year] [int(11)]	[cigar_pipe_qty_p er_day] [int(11)]
chewing tobacco (in paan masala, paan, other mix)	[] [] [chewing_tobacco_regul ar_use] [int(11)] [Yes=1; No=2]	[] [] [chewing_tobacco_pas t_use] [int(11)] [Yes=1; No=2]	[chewing_tobacco_no_ of_year] [int(11)]	[chewing_tobacco _qty_per_day] [int(11)]
Other:	[] [] [other_regular_use] [int(11)] [Yes=1; No=2]	[] [] [other_past_use] [int(11)] [Yes=1; No=2]	[other_no_of_year] [int(11)]	[other_qty_per_da y] [int(11)]

 10.06
 Ever drink alcohol
 [] Y
 Continue below
 [Yes=1; No=2]

 [] ever_drink_alcohol]
 [int(11)]
 [] N
 Skip to Section 11
 Commented [CR30]: If the response is[No 2] skip to Q.no.11 (Selfcare)

[]Y []N	Currently drink alcohol once a week or more (for most weeks in past year)
	[currt_drink_alcohol] [int(11)] [Yes=1; No=2]
[]Y []N	Used to drink alcohol regularly in the past
	[drink_alcohol_regularly_past] [int(11)] [Yes=1; No=2]
	Number of years of alcohol use
	[no_year_alcohol] [int(11)] [No data in this field]
	Average days per week of alcohol use (current/past)
	[aveg_day_week_drink] [int(11)]
	Average drinks per day (current/past)
	One drink: wine=100 ml, spirit=30 ml, beer=330 ml
	[aveg_per_day_drink] [int(11)] [aveg_drink_wine_week] [int(11)] [aveg_drink_spirits_week] [aveg_drink_beer_week] {doubt in this 2 fields}
	Most drinks in one day in past 3 months (0 if not currently drinking)
	[aveg_most_drink] [int(11)]

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 15 of 28

Commented [CR29]: If the response is [No 2] skip to Q.no.10.06

11. Self-Care - Data saved in "patient_self_care.csv" & "patient_selfcare_form_c.csv" and is in long format

The questions below ask you about your diabetes self-care activities during the past 7 days.

If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET												
11.01	On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?	0	1	2	3	4	5	6	7			
11.02	[self_care_id=2] [int(11)] [01234567]	_										
11.02	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?		1	2	3	4	5	6	7			
	[self_care_id=3] [int(11)] [0 1 2 3 4 5 6 7]											
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products? [self_care_id=4] [int(11)] [0 12 3 4 5 6 7]	0	1	2	3	4	5	6	7			
11.04	On how many of the last SEVEN DAYS did you space eating meals evenly through the day?	0	1	2	3	4	5	6	7			
	[self_care_id=5] [int(11)] [0 1 2 3 4 5 6 7]											
EXERC	ISE											
11.05	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)		1	2	3	4	5	6	7			
	[self_care_id=6] [int(11)] [0 1 2 3 4 5 6 7]											
11.06	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?		1	2	3	4	5	6	7			
	[self_care_id=7] [int(11)] [0 1 2 3 4 5 6 7]											
BLOOD	SUGAR TESTING											
11.07	Are you testing your blood sugar as recommended by your health care provider?	0[] No] Ye				okin t	to 11.09)				
	[self_care_id=9] [int(11)] [Yes 1, No 0, N/A -1]	1] 16	5 2	.[]	N/A (sкiр i	011.	09)			
11.08	On how many of the last SEVEN DAYS did you test your blood sugar?	0	1	2	3	4	5	6	7			
	[self_care_id=8] [int(11)] [0 1 2 3 4 5 6 7]											
MEDIC	ATIONS											
11.09	On how many of the last SEVEN DAYS, did you take your recommended <u>diabetes medication</u> ? (pills and/or insulin) [self_care_id=10] [int(11)] /0.12.3.4.5.6.7]		1	2	3	4	5	6	7			
FOOT	CARE	-1										
11.10	On how many of the last SEVEN DAYS did you check your feet?		1	2	3	4	5	6	7			
	[self_care_id=11] [int(11)] [0 1 2 3 4 5 6 7]											
TOBAC	000											
11.11	Ever smoke regularly? (most days of the week)											
	[self_care_id=12] [int(11)] [never 0, quit 1, Yes 2] [if quit 1] → [quit smoking year] [varchar(20)]	uit:					_ (MN	1M/yy	vyy)			
	$[if yes 2] \rightarrow [smoke_per_day] [int(11)] 2[] Y$	es, # :	smok	ed pe	er day	/:	-					

Commented [CR31]: In Self-care section data is saved in 2 files 1. "patient_self_care.csv" & 2." patient_selfcare_form_c.csv and unique ID is "Self_care_id "

CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010

Page 16 of 28

Commented [CR32]: If the response is [quit 1] specify the year & response is [yes 2] specify no. smoked per day

11.12	Ever chew tobacco regularly? (most days of the week) [self_care_id=13] [int(11)] [never 0, quit 1, Yes 2] [if quit 1] → [quit_tobacco_year] [varchar(20)] [if yes 2] → [packet_per_day] [int(11)]		/ (MMM/yyyy) # packets per day:		CR33]: If the response is [quit 1] specify the year s 2] specify no. packet per day
11.13	If you smoke or chew tobacco, at your last doctor's visit, did anyone counsel you about stopping or refer you to counseling? [self_care_id=14] [int(11)] [N/A 0, yes 1, no 2]	0[]No 1[]Yes	2[]N/A		
ALCOH	IOL				
11.14	Drink alcohol regularly? (at least once a week for most weeks in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] [never 0, yes 1]		0 [] No 1 [] Yes, # drinks per day:		
07050	$[if yes 1] \rightarrow [drink_per_day] [int(11)]$			Commented [0 drink per day	CR34]: If the response is [yes 1] specify no.
STRES					
11.15	How often do you feel stress (from work, responsib [] daily [] few times a week [self_care_id=16] [int(11)] [daily 1, few times a week 2, few tii	Commented [CR35]: Responses at backend for this variable are			
11.16	How are you coping with stress? [] very well] moderate [] with difficulty [] not applicable (no stress) [self_care_id=17] [int(11)] [very well 1, moderate 2, with difficulty 3, not applicable(no stress) 4]			saved as [0 1 2 3 4] but , there is no category for '0' Commented [CR36]: Responses at backend for this variable are	
				saved as [0 1 2 3 d but, there is no ca	
12.	EQ-5D - Data saved in "eq_5d.csv" and is in wide form	at			
Place a	tick in one box in each group below for the statement the	at best desc	ribes your own health state today.		
12.01	Mobility [I have no problems in walking about 1, 11] [mobility_id] [int (11)] I am confined to bed 3] 1 I have no problems in walking about 2 I have some problems in walking about 2 I have some problems in walking about 2	have some pro	blems in walking about 2,		

3 I am confined to bed

12.02 Self-Care [I have no problems with self-care 1, I have some problems with self-care 2,

[self_care_id] [int(11)] I am unable to wash or dress myself 3]

- 1 I have no problems with self-care
- 2
 I have some problems with self-care
- $3 \Box$ I am unable to wash or dress myself

12.03 Usual Activities (e.g. work, study, housework, family or leisure activities)

[usual_activities] [int(11)] [I have no problems with performing my usual activities 1,

- I have some problems with performing my usual activities 2,
- I am unable to perform my usual activities 3]
- 1 I have no problems with performing my usual activities
- 2 \square I have some problems with performing my usual activities
- 3 🗆 I am unable to perform my usual activities

12.04 Pain/Discomfort

[pain_discomfort] [int(11)] [I have no pain or discomfort 1, I have moderate pain or discomfort 2, I have extreme pain or discomfort 3]

- 1 □ I have no pain or discomfort
- 2 \Box I have moderate pain or discomfort
- $3 \square I$ have extreme pain or discomfort

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 17 of 28
12.05 Anxiety/Depression

[anxiety_depression] [int(11)] [I am not worried or depressed 1, I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]

- 1 🗆 I am not worried or depressed
- 2 \Box I am moderately anxious or depressed
- 3 🗆 I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.



CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

13. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale. How satisfied are you with your current treatment? 13.01 [current_treatment] [int] [0, 1, 2, 3, 4, 5, 6] Very satisfied Very dissatisfied 2[] 1[] 6[] 5[1 4[] 3[1 0[] 13.02 How often have you felt that your blood sugars have been unacceptability high recently? [blood_sugar_high] [int] [0, 1, 2, 3, 4, 5, 6] Most of the time None of the time 5[] 3[] 2[] 6[] 4[] 1[] 0[] 13.03 How often have you felt that your blood sugars have been unacceptability low recently? [blood_sugar_low] [int] [0, 1, 2, 3, 4, 5, 6] Most of the time None of the time 5[] 4[] 3[] 2[] 1[] 0[] 6[] 13.04 How convenient have been finding your treatment to be recently? [convienent_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very convenient Very inconvenient 6[] 5[] 4[] 3[] 2[] 1[] 0[] How flexible have you been finding your treatment to be recently? 13.05 [flexible_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very inflexible Very flexible 6[] 5[] 4[] 3[] 2[] 1[] 0[] 13.06 How satisfied are you with understanding of your diabetes? Very satisfied Very dissatisfied 4[] 3[] 2[] 6[] 5[] 1[] 0[] How satisfied would you be to continue with your present form of diabetes treatment? 13.07 [present_dib_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very satisfied Very dissatisfied 3[] 2[] 1[] 5[] 4[] 0[] 6[] Would you recommend this form of treatment to someone else? 13.08 [recommend_form] [int] [0, 1, 2, 3, 4, 5, 6] Yes, I would No, I would definitely definitely NOT recommend recommend this treatment this treatment 4[] 3[] 2[] 1[] 6[] 5[] 0[]

14. Health Utilities Index

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] [1, 2, 3, 4]

- 1 a. Able to see well enough without glasses or contact lenses
- 2 b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses

4□ d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] [1, 2, 3, 4]

- 1 a. Able to see well enough without glasses or contact lenses
- 2 b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses

4 d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] [1, 2, 3, 4, 5]

- 1 a. Able to hear what was said without a hearing aid
- 2D b. Able to hear what was said with a hearing aid
- 3 c. Unable to hear what was said even with a hearing aid.
- 4 d. Unable to hear what was said, but did not wear a hearing aid
- 5 e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a guiet room?

[other_person_conversation] [int] [1, 2, 3, 4, 5]

- 1 a. Able to hear what was said without a hearing aid
- 2D b. Able to hear what was said with a hearing aid
- 3 c. Unable to hear what was said even with a hearing aid
- 4 d. Unable to hear what was said, but did not wear a hearing aid
- 5D e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] [1, 2, 3, 4]

- 1 a. Able to be understood completely
- 2 b. Able to be understood partially 3 c. Unable to be understood
- 4 d. Unable to speak at all
- 14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] [1, 2, 3, 4]

- 1 a. Able to be understood completely.
- 20 b. Able to be understood partially.
- 3 c. Unable to be understood.
- 4 d. Unable to speak at all.

14.07. Which one of the following best describes how you have been feeling during the past 4 weeks?

[feeling] [int] [1, 2, 3, 4, 5]

- 1 a. Happy and interested in life
- 2D b. somewhat happy
- 3 c. somewhat unhappy
- 4□ d. Very unhappy
- 5 e. So unhappy that life was not worthwhile

CARRS Translation Trial; Form C - Baseline_Randomization v1.4-3DEC2010

Page 20 of 28

14.08. Which one of the following best describes the pain and discomfort you have experienced during the past 4 weeks?

[discomfort_exp] [int] [1, 2, 3, 4, 5]

1□ a. Free of pain and discomfort

2 b. Mild to moderate pain or discomfort that prevented no activities.

3 c. Moderate pain or discomfort that prevented a few activities

4 d. Moderate to severe pain or discomfort that prevented some activities

5 e. Severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] [1, 2, 3, 4, 5, 6]

1 a. Able to walk around the neighborhood without difficulty, and without walking equipment

2 b. Able to walk around the neighborhood with difficulty; but did not require walking equipment

or the help of another person

3 c. Able to walk around the neighborhood with walking equipment, but without the help of another person 4 d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood

5 c. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood

6 f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.)
[hands_finger] [int] [1, 2, 3, 4, 5, 6]

1□ a. Full use of hands and ten fingers

2 b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person

3 . Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)

4 d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)

 $5\square$ e. Limitations in the use of hands or fingers, required the help of another person for most tasks (not

independent even with use of special tools)

6 f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] [1, 2, 3, 4]

 $1\square$ a. Able to remember most things

2□ b. Somewhat forgetful

3□ c. Very forgetful

4□ d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] [1, 2, 3, 4, 5]

- 1 a. Able to think clearly and solve day to day problems
- 2D b. Had a little difficulty when trying to think and solve day to day problems
- $3\square$ c. Had some difficulty when trying to think and solve day to day problems
- $4\square$ d. Had great difficulty when trying to think and solve day to day problems
- $5\square$ e. Unable to think or solve day to day problems

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 21 of 28

14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] [1, 2, 3, 4]

1□ a. Eat, bathe, dress and use the toilet normally

2D b. Eat, bathe, dress and use the toilet independently with difficulty

3 c. Required mechanical equipment to eat, bathe, dress or use the toilet independently

4 d. Required the help or another person to eat, bathe, dress or use the toilet

14.14. Which one of the following best describes how you have been feeling during the past 4 weeks? [feeling_health_utility] [int] [1, 2, 3, 4]

1 a. Generally happy and free from worry

2 b. occasionally fretful, angry, irritable, anxious or depressed

3 c. often fretful, angry, irritable, anxious or depressed

4 d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

[discomfort_health_utility] [int] [1, 2, 3, 4, 5]

1 a. Free of pain and discomfort

2 b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities

3 C. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities

4 d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief

5 e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15. Processes of Care

In the past 12 months, how often did the following occur (EXCLUDE current visit):

		Indicate number	Month of last visit/test/exa (MMM/yyyy)	m
15.01	Clinic Visits [fpc_clinic_visit_indicate_no] [int(11)]		/	[]unknown
	[fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] [-1]			
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] [-1]		/	[]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)] [fpc_cholestrol_testing_unknown] [int(11)] [-1]		/	[]unknown
15.04	Foot Exam at clinic [fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] [-1]		1	[]unknown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] [-1]		/	[]unknown

Commented [r37]: The dates for the below listed variables are generated by the system in YY-MMM format: [fpc_thinc_visit_month_of_visit] [fpc_hba_testing_month_of_visit] [fpc_cholestrol_testing_month_of_visit] [fpc_eve_exam_month_of_visit] [fpc_microal_check_month_of_visit] [fpc_dental_exam_month_of_visit] [fpc_dental_exam_month_of_visit] [fpc_dietician_visit_month_of_visit] [fpc_dietician_visit_month_of_visit]

Indicate number, Month of last visit & unknown If response is [unknown] data is saved as '-1'

CARRS Translation Trial; Form C - Baseline_Randomization v1.4-3DEC2010

Page 22 of 28

15.06 Microalbuminuta check					
ipc.microal_check_indicate_no] [int(15)] interval_interv	15.06	Microalbuminuria check		1	[]unknown
ipc_microal_check_month_of_visit[varchar(15)]	10.00			/	[]amaiomi
ipc_microal_check_unknown [int(13)]:-:i)			15)]		
15.07 ECG [interline] [interline] [interline] 15.07 ECG [interline] [interline] [interline] 15.08 Dental Exam [interline] [interline] [interline] 15.08 Dental Exam [interline] [interline] [interline] [interline] 15.09 Detician/Diabetes Education [interline] [interline] [interline] [interline] 15.09 Detician/Diabetes Education [interline] [interline] [interline] [interline] 15.00 Other than your current diabetes physician, how many other doctors do you see regularly for care?					
Ipc_esg_indicate_no] [ini(1)] Image: Signature Sig	15.07			/	[]unknown
Ipc_ecg_month_of_visit[varchar(15)] Ipc_ecg_exam_unknown] [im(11)] /-1/ 15.08 Dental Exam Ipc_ectal_exam_indicate_no] [im(11)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectal_exam_month_of_visit[varchar(15)] Ipc_ectatican_visit_unknown] [im(11)] Ipc_ectatican_visit_unknown] Ipc_ectatican_visit_unknown] [im(11)] Ipc_ectatican_visit_unknown] Ipc_ectatican_visit_unknown] [im(11)] Ipc_ectatican_visit_unknown] Immin_visit_unknown] 15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care?	10.01			/	
Ifpc_ecg_exam_unknown [int(11)]					
15.08 Dental Exam [int(11)] [int(11)] [int(11)] [int(11)] 15.09 Dietician/Diabetes Education [int(11)] [int[int] [intint] [int(11)] [int[int(
Ifpc_dental_exam_month_or_visit[Varchar(15)] Image: Control (Control (Contre))))))))))))))))))))))))))))))))))))	15.08			/	[]unknown
ipc_dental_exam_month_of_visit ivarchar(15) ipc_dental_exam_unknown imt(11) [-1] 15.09 Dietician/Diabetes Education ipc_dietician/Diabetes Education ipc_dietician/Diabetes Education 15.00 Other than your current diabetes physician, how many other doctors do you see regularly for care? ipt_citician_visit_unknown [imt(11)] [-1] 15.10 Other doctors_count] [imt(11)] ipt_citician_visit_unknown [imt(11)] ipt_citician_visit_unknown [imt(11)] 01 average: ipt_citician_visit_unknown [imt(11)] ipt_citician_visit_unknown [imt(11)] ipt_citician_visit_unknown [imt(11)] 01 average: ipt_citician_visit_unknown [imt(11)] ipt_citician_visit_unknown [imt(11)] ipt_citician_visit_unknown [imt(11)] 15.11 Total time spend commuting to clinic – ONE WAY					[]]
ipc_dental_exam_unknown [int(11)] /-1/ 15.09 Dietcian/Diabetes Education			5)]		
15.09 Dietician/Diabetes Education [fpc_dietician_visit_indicate_no] [int(11)] [fpc_dietician_visit_unknown[[int(11)]] [fpc_dietician_visit_unknown[[int(11)]]			-//		
[fpc.dietician_visit_month_of_visit][varchar(15)] Image: Content of the image: Content	15.09			/	[]unknown
Ipc_dietician_visit_month_of_visit] [varchar(15)] Ipc_dietican_visit_unknown[imt(11)] /-1/ 15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care? [other_doctors_count] [imt(11)] On average: 15.11 Total time spend commuting to clinic – ONE WAY					
(fpc_dietician_visit_unknown) [int(11)] [-:1] 15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care? [other_doctors_count] [int(11)] On average: 15.11 Total time spend commuting to clinic – ONE WAY			5)]		
15.10 Other than your current diabetes physician, how many other doctors do you see regularly for care? (atter_doctors_count] [int(11)] On average:					
[ather_doctors_count] [int(11)] On average:	15.10 O		many other doctors do	o vou see regularly f	or care?
On average: 15.11 Total time spend commuting to clinic – ONE WAY				,	
15.11 Total time spend commuting to clinic – ONE WAY					
[time_commuting] [int(11)] 15.12 Total time spend for lab tests, include waiting (if done same day)min [lab_test] [int(11)] min 15.13 Total time spend waitingfor consultationmin [wait_consult] [int(11)] min 15.14 Total time spend in-person with doctormin [in_person_doc] [int(11)] min 15.15 Total time with dietician, nurse or clinic-staff receiving self-care educationmin [self_care_edu] [int(11)] min 15.16 Other time for check-out, getting medications, etc (at end of visit)min [other_time] [int(11)] min 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [int(11)] min 15.17 What type of reminder for next visit, referral or lab investigation (at current visit) 2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations		0	AY		min
15.12 Total time spend for lab tests, include waiting (if done same day) min [lab_test] [int(11)] min 15.13 Total time spend waitingfor consultation min [wait_consult] [int(11)] min 15.14 Total time spend in-person with doctor min [in_person_doc] [int(11)] min 15.15 Total time with dietician, nurse or clinic-staff receiving self-care education min [self_care_edu] [int(11)] min 15.15 Total time for check-out, getting medications, etc (at end of visit) min [other time for check-out, getting medications, etc (at end of visit) min min [other time] [int(11)] 15.16 Other time for next visit, referral, or lab investigation (at current visit) 15.17 What type of reminder for next visit, referral or lab investigation (at current visit) 1 1] Verbal reminder for next visit, referral or lab investigation (at current visit) 1 2] Written reminder for next visit, referral or lab investigation (at current visit) 1 3 [Phone call for upcoming appointment (clinic or referral) 4 4 [Phone call tog of rab investigations					
[lab_test] [int(11)] 15.13 Total time spend waitingfor consultation			if done same day)		min
15.13 Total time spend waitingfor consultation					
[wait_consult] [int(11)] 15.14 Total time spend in-person with doctor min [in_person_doc] [int(11)] 15.15 Total time with dietician, nurse or clinic-staff receiving self-care education min [self_care_edu] [int(11)] 15.16 Other time for check-out, getting medications, etc (at end of visit) min [other_time] [int(11)] min 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 11] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2] Written reminder for next visit, referral or lab investigation (at current visit) 3] Phone call for upcoming appointment (clinic or referral) 4 [Phone call to go for lab investigations 6] Mailing for missed appointment (clinic or referral) 7] Mailing for missed appointment (clinic or referral) 8] other, specify:					min
15.14 Total time spend in-person with doctor min [in_person_doc] [int(11)] 15.15 Total time with dietician, nurse or clinic-staff receiving self-care education min [self_care_edu] [int(11)] 15.16 Other time for check-out, getting medications, etc (at end of visit) min [other_time] [int(11)] 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 11 I Verbal reminder for next visit, referral or lab investigation (at current visit) 2 I Written reminder for next visit, referral or lab investigation (at current visit) 2 I Written reminder for next visit, referral or lab investigation (at current visit) 2 I Written reminder for next visit, referral or lab investigation (at current visit) 2 I Written reminder for next visit, referral or lab investigation (at current visit) 3 I Phone call for upcoming appointment (clinic or referral) 4 I Phone call to go for lab investigations 6 I Mailing for missed appointment (clinic or referral) 7 I Mailing to go for lab investigations 9 I other, specify:					
[in_person_doc] [int(11)] 15.15 Total time with dietician, nurse or clinic-staff receiving self-care educationmin					min
15.15 Total time with dietician, nurse or clinic-staff receiving self-care education					
[self_care_edu] [int(11)] 15.16 Other time for check-out, getting medications, etc (at end of visit) min [other_time] [int(11)] 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 1] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2] Written reminder for next visit, referral or lab investigation (at current visit) 3[] Phone call for upcoming appointment (clinic or referral) 4[] Phone call to go for lab investigations 6[] Mailing for upcoming appointment (clinic or referral) 7[] Mailing for upcoming appointment (clinic or referral) 8[] Phone call to go for lab investigations 9[] other, specify:				ation	min
15.16 Other time for check-out, getting medications, etc (at end of visit)min			ceiving self-care educa		
iother_time] [int(11)] 15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) (type_of_reminder] [iype_of_reminder] [varchar (20)] 1] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call to go for lab investigations 5 [] Phone call to go for lab investigations 6 [Mailing for upcoming appointment (clinic or referral) 7 [Mailing to go for lab investigations 8 [Mailing to go for lab investigations 9 [] other, specify:			ata (at and of visit)		min
15.17 What type of reminders do you receive from the clinic for your care? (check all that apply) [type_of_reminder] [varchar (20)] 1] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2] Written reminder for next visit, referral or lab investigation (at current visit) 3] Phone call for upcoming appointment (clinic or referral) 4] Phone call i missed appointment (clinic or referral) 5] Phone call to go for lab investigations 6] Mailing for upcoming appointment (clinic or referral) 7] Mailing to go for lab investigations 8] Mailing to go for lab investigations 9] other, specify:			eic (al end of visit)		
[type_of_reminder] [varchar (20)] 1 [] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call if missed appointment (clinic or referral) 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:			a aliaia far your aara?	(abook all that apply	A
1 [] Verbal reminder for next visit, referral, or lab investigation (at current visit) 2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:			e clinic for your care?	спескал пагарру)
2 [] Written reminder for next visit, referral or lab investigation (at current visit) 3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call if missed appointment (clinic or referral) 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:			atigation (at ourrant via	.:+)	
3 [] Phone call for upcoming appointment (clinic or referral) 4 [] Phone call if missed appointment (clinic or referral) 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:			-		
4 [] Phone call if missed appointment (clinic or referral) 5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:				sit)	
5 [] Phone call to go for lab investigations 6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:					
6 [] Mailing for upcoming appointment (clinic or referral) 7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:			(I)		
7 [] Mailing for missed appointment (clinic or referral) 8 [] Mailing to go for lab investigations 9 [] other, specify:			-1)		
8 [] Mailing to go for lab investigations 9 [] other, specify:	• •		ai)		
I other, specify:	• •	o ,			
[other_reminder] [varchar (20)] 16. Costs of Care 16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR: Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket		0 0 0			
16. Costs of Care 16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR: Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket					
16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR: Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket		[other_reminder] [varchar (20)]			
Outpatient visits? Inpatient care? % Out-of-pocket % Out-of-pocket	16.	Costs of Care			
% Out-of-pocket% Out-of-pocket	16.01	What are your sources of finance (give percen	ages, indicate '0' if no	t used) FOR:	
	Outpatie	ent visits?	Inpatient care?		
	%	o Out-of-pocket	% Out-of-poc	ket	
CARRS Translation Trial; Form C – Baseline_Randomization v1.4-3DEC2010 Page 23 of 28					

[out_of_pocket_opd] [double] % Employer Insurance [employer_insurance_opd] [double] % Private Insurance_opd] [double] % Government insurance, non-job based [govt_insurance_opd] [double] % Other, please specify: [other_opd] [double] [other_details_opd] [varchar(200)] = 100 % total	[out_of_pocket_ipd] [double] % Employer Insurance [employer_insurance_ipd] [double] % Private Insurance [private_insurance_ipd] [double] % Government insurance, non-job based [govt_insurance_ipd] [double] % Other, please specify: [other_ipd] [double] [other_ipd] [double] [other_details_ipd] [varchar(200)] =100 % total
OUTPATIENT CARE	

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1 year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization. EXCLUDE current visit.

- 16.03 How many days, including half days, did you miss from work
- for outpatient visits in the past 1 year? _____ days [] N/A

[days_miss_work] [int(11)] [days_miss_work_na] [int(11)] [1]

16.04 List all persons who accompanied you to outpatient visits in the past 1 year: This data is in file "patient_accompained_visit" & is in long format

Person Relation (e.g. father)	Occupation	Monthly salary	Number visits accompanied
[person_relation]	(number*)	[monthly_salary]	[number_of_visit]
	[occupation]		

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item	Number	Average cost
		of times	One-time (Rupees)
16.05	Consultation Fee		
	[con_fee_frq] [int(11)] [avg_con_fee] [double]		
16.06	Lab Tests (HbA1c, blood glucose, urine check)		
	[lab_test_frq] [int(11)] [avg_lab_test] [double]		
16.05	Eye Exam		
	[eye_eam_frq] [int(11)] [avg_eye_exam] [double]		
16.06	ECG		
	[ecg_frq] [int(11)] [avg_ecg_fee] [double]		
16.07	Medicines (tablets, insulin)		
	[med_frq] [int(11)] [avg_med_fee] [double]		

CARRS Translation Trial; Form C – Baseline_Randomization v1.4- 3DEC2010

Page 24 of 28

Commented [CR39]: One more variable available for questions 16.05 to 16.12 "Total cost" and values also stored for this variable

		1	
16.08	Supplies (including glucose strips, gauze, sterile solution,		
	etc.)		
	[supply_frq] [int(11)] [avg_supply_fee] [double]		
16.09	Transportation		
	[transport_frq] [int(11)] [avg_transport] [double]		
16.10	Food (personal)		
	[food_personal_frq] [int(11)] [avg_food_personal] [double]		
16.11	Additional cost for escort(s) (e.g. food)		
	[escorts_freq] [int(11)] [avg_escorts] [double]		
16.12	Other out-of-pocket expenses		
	[outpocket_frq] [int(11)] [avg_outpocket_exp] [double]		
	· · · · · · · · · · · · · · · · · · ·		

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetesrelated complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year?

[hospital_emergency] [int(11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below – (Make sure that visits listed below equals total number listed in 16.13) When providing time, include half-days. This data is in file "patient_hospitalization_visit" & is in long format

	TYPE	Days of	Hospital	Cost	Transpo	ortation	Food Cost	Additional	Person(s) accompanied (Escort) – list all		
	1=	stay	including		Cost,		[food_cost]	Escort(s) Cost		,		
	Hospitalization,	-	medicine/		includin	a	[]	[escorts_cost]				
		[ddiddoi]				-			Deletier	Occurretien	Manthly Calany	Deve eccentration
	NO surgery		supplies		ambula				Relation	Occupation	Monthly Salary	Days accompanied
	2= Surgery		(total	stay)	fees	(total			[person_accompained]	(number*)	[monthly_salary]	[days_person_accompained]
	3= Emergency		[hospital_	_cost]	stay)					[occupation]		
	Room [reason]				[transp	ort]						
1												
2												
2												
3												
4												

5						
_						
6						

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

17. Other Contacts

This data is confidential

Please list 2 contacts who do not live with you and would know where and how we can contact you. *mandatory fields

17.01	Contact 1	
Name		First:*
		Middle:
		Last:*
Mailing Ad	ldress	Address 1:*
		Address 2:
		City:*
		Pin code:*
		State.*
Mobile*		91
Phone 2		
Email ID		
Relation (e.a. father. friend) *	

17.02	Contact 2	
Name		First:*
		Middle:
		Last.*
Mailing A	ddress	Address 1:*
		Address 2:
		City:*
		Pin code:*
		State:*
Mobile*		91
Phone 2		
Email ID		
Relation (e.g. father, friend) *	

18. Care Coordinator/Research Officer Signature

18.01 Name: _

_____ Signature:

18.03 DSS Instructions:

(1) Enroll patient in DSS \rightarrow Login. Select **Enroll patient** from left panel. Enter information and click on **Enroll** at bottom of page.

(2) Enter rest of Forms B and Form C in eCRFs found on patient main page.

CARRS Translation Trial; Form C - Baseline_Randomization v1.4- 3DEC2010

Page 28 of 28

• FORM E - Follow-up 12 monthly_All

- ٠
- All dates **dd/MMM/yyyy (e.g. 31/DEC/2010)** Place cross [X] in the appropriate boxes. Write number in spaces (f none, write 0) •
- •
- See Form Completion Notes, for definitions and explanations Store copies of available source documents (SD), where indicated, in patient's trial folder ٠

PART 1: To be completed by CARE COORDINATOR or RESEARCH OFFICER

Data entry by:	Screening ID: S
[data_entry_by] [varchar (100)]	
Initials	Participant ID:
DATE entered: / /	[participant_id] [varchar (20)]
	Date of Visit (dd/MMM/yyyy): / / / /
	[date of visit] [date]

FORM E - Data saved in "patient_forme.csv" and is in long format

1. Int	ake						
A1.01	A1.01 Complaints/Update:						
	[complaints] [varchar(500)]						
1.02-1.04	For intervention group/care coordinator only:						
A1.02	Number of severe hypoglycemic episodes since last visit (If present, complete Form X)						
	[severe_hg_count] [int(11)]						
A1.03	Number of mild hypoglycemic episodes since last visit						
	[mild_hg_count] [int(11)]						
A1.04	Other SAE since last visit (If present, complete Form X with investigator)	[]Y	[]N		
	[other_sae] Yes=1, No=2						

2. Measures

B1.02	Heart rate	(beats/min)
	[heart_rate] [int(11)]	
B1.03	Blood pressure 2 nd reading	/ (mmHg)
	[blood_pressure_h_1] [int(11)] / [blood_pressure_l_1] [int(11)]	
B1.04	Blood pressure 3 rd reading	/ (mmHg)
	[blood_pressure_h_2] [int(11)] / [blood_pressure_l_2] [int(11)]	
B1.06	Waist circumference	(cm)
	[waist_circumference] [double]	
B1.07	Weight	(kg)
	[weight] [double]	

Investigations 3.

B2.04	Hemoglobin A1c [hemoglobin_a1c] [double]	%	Date:/ / [hemoglobin_a1c_date] [date]
B2.10	Fasting blood glucose (venous) [fasting_blood_glucose_mgdl] [double]	(mg/dL)	Date:/ / / [fasting_blood_glucose_date] [date]
B2.13	Post-prandial blood glucose (venous) – optional	(mg/dL)	Date:/// [post_prandial_blood_glu_date] [date]

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 1 of 23

			1
	[post_prandial_blood_glu] [double]		
B2.05	ALT – optional	(units/L)	Date: / / /
	[alt] [double]		[alt_date] [date]
A2.06	Total Cholesterol	(mg/dL)	Date: / / /
	[total_cholesterol] [double]		[total_cholesterol_date] [date]
B2.07	HDL Cholesterol	(mg/dL)	Date: / / /
	[hdl_cholesterol] [double]		[hdl_cholesterol_date] [date]
B2.08	LDL Cholesterol (indirect)	(mg/dL)	Date: / / /
	[ldl_cholesterol] [double]		[Idl_cholesterol_date] [date]
B2.09	Triglycerides	(mg/dL)	Date: / / /
	[triglycerides] [double]		[triglycerides_date] [date]
B2.02	Sodium – optional	(mEq/L)	Date: / / /
	[sodium] [double]		[sodium_date] [date]
B2.03	Potassium – optional	(mEq/L)	Date: / / /
	[potassium] [double]		[potassium_date] [date]
B2.01	Creatinine		Date: / / /
	[creatinine_mg] [double]	(mg/dL)	[creatinine_date] [date]
B2.12	Albumin:creatinine ratio	<u></u>	Date: / /
	[s_albumin_mg] [double]	(mg/g)	[s_albumin_date] [date]

11. Self-Care - Data saved in "patient_selfcare_e.csv" & "patient_selfcare_form_e.csv" files & they are in wide format and long formats

The questions below ask you about your diabetes self-care activities <u>during the past 7 days</u>. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET									
11.01	On average, over the past month, how many DAYS PER WEEK have you followed your diet plan?	0	1	2	3	4	5	6	7
	[self_care_id=2] [int(11)] [0 1 2 3 4 5 6 7]								
11.02	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?	0	1	2	3	4	5	6	7
	[self_care_id=3] [int(11)] [0 1 2 3 4 5 6 7]								
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products?	0	1	2	3	4	5	6	7
	[self_care_id=4] [int(11)] [0 1 2 3 4 5 6 7]								
11.04	On how many of the last SEVEN DAYS did you space eating meals evenly through the day?	0	1	2	3	4	5	6	7
	[self_care_id=5] [int(11)] [0 1 2 3 4 5 6 7]								
EXERC	ISE								
11.05	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)	0	1	2	3	4	5	6	7
	[self_care_id=6] [int(11)] [0 1 2 3 4 5 6 7]								
11.06	On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?	0	1	2	3	4	5	6	7
	[self_care_id=7] [int(11)] [0 1 2 3 4 5 6 7]								
CARRSI	Translation Trial: Form F - Follow-up 12 monthly All v14-3DEC2010		Pa	ane 2	of 23	ł			

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 2 of 23

Commented [CR1]: In Self-care section data is saved in 2 files 1. "patient_self_care_e.csv " & 2." patient_selfcare_form_e.csv and unique ID is "self_care_id "

	SUGAR TESTING										
11.07	Are you testing your blood sugar as recommended health care provider? [self_care_id=9] [int(11)] [Yes 1, No 0, N/A -1]	d by your] No] Ye		2[]	N/A ((skip 1	to 11.	.09)	
11.08	On how many of the last SEVEN DAYS did you test yo sugar? [self_care_id=8] [int(11)] [0 1 2 3 4 5 6 7]	our blood	0	1	2	3	4	5	6	7	-
MEDIC	ATIONS										
11.09	On how many of the last SEVEN DAYS, did you tak recommended <u>diabetes medication</u> ? (pills and/or in [self_care_id=10] [int(11)] [0 12 3 4 5 6 7]		0	1	2	3	4	5	6	7	
FOOT	CARE										
11.10	On how many of the last SEVEN DAYS did you check feet? [self_care_id=11] [int(11)] [0 1 2 3 4 5 6 7]	your	0	1	2	3	4	5	6	7	
TOBAC	CO										
11.11	Ever smoke regularly? (most days of the week) [self_care_id=12] [int(11)] [never 0, quit 1, Yes 2] [if quit 1] → [quit_smoking_year] [varchar(20)] [if yes 2] → [smoke_per_day] [int(11)]	0[]Ne 1[]Qu 2[]Ye	iit:						/М/у	ууу)	Commented [CR2]: If the response is [quit 1] specify the year response is [yes 2] specify no. smoked per day
11.12	Ever chew tobacco regularly? (most days of the week) [self_care_id=13] [int(11)] [never 0, quit 1, Yes 2] [if quit 1] → [quit_tobacco_year] [varchar(20)] [if yes 2] → [packet_per_day] [int(11)]	0[]No 1[]Qu 2[]Ye	iit					_ (MM	IM/yy	yy)	Commented [CR3]: If the response is [quit 1] specify the year response is [yes 2] specify no. packet per day
11.13	If you smoke or chew tobacco, at your last doctor's visit, did anyone counsel you about stopping or refer you to counseling? [self_care_id=14] [int(11)] [N/A 0, Yes 1, no 2]	0[]No 1[]Ye		2 [] N/	Ά					
ALCOH	OL										
11.14	Drink alcohol regularly? (at least once a week for mo in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] [never 0, Yes 1] [if yes 1] \rightarrow [drink_per_day] [int(11)]	ost weeks	-] N] Y		drinł	s pe	r day	:		Commented [CR4]: If the response is [yes 1] specify no. dr
STRES			-								per day
11.15	How often do you feel stress (from work, responsil [] daily [] few times a week [self_care_id=16] [int(11)] (daily 1, few times a week 2, few ti	[] few	time		nonth	I		[]n	ever		Commented [CR5]: Responses at backend for this variable a
11.16	Image: Self_care_id=10] [mit(11)] [pany 1, rew times a week 2, rew times a month 3, never 4] How are you coping with stress? [] [] not applicable (no stress) [] very well [] moderate [] with difficulty [] not applicable (no stress) [self_care_id=17] [int(11)] [very well 1, moderate 2, with difficulty 3, not applicable(no stress) 4]						saved as [0 1 2 3 4] but, there is no category for '0' Commented [CR6]: Responses at backend for this variable a saved as [0 1 2 3 4] but, there is no category for '0'				

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 3 of 23

10. Lifestyle – Data is saved in "patient_life_style.csv" and is wide format

10.05	Diet (weekday/ routine day)	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6	
	Meal Time (approximate)	[meal1_ampm] [varchar(6)] [AM or PM]	[meal2_ampm] [varchar(6)] [AM or PM]	[meal3_ampm] [varchar(6)] [AM or PM]	[meal4_ampm] [varchar(6)] [AM or PM]	[meal5_ampm] [varchar(6)] [AM or PM]	[meal6_ampm] [varchar(6)] [AM or PM]	
		_:amPm	_:amPm	:amPm	_:amPm	_:amPm	_:amPm	Commented [CR7]: Should specify [AM or PM]
		[meal1_time] [varchar(5)]	[meal2_time] [varchar(5)]	[meal3_time] [varchar(5)]	[meal4_time] [varchar(5)]	[meal5_time] [varchar(5)]	<mark>[meal6_time]</mark> [varchar(5)]	
								Commented [CR8]: Should specify time of the meal
	Type B=breakfast,	[meal1_type]	[meal2_type]	[meal3_type]	[meal4_type]	[meal5_type]	[meal6_type]	
	L=lunch, D=dinner, S=snack	[varchar(6)]	[varchar(6)]	[varchar(6)]	[varchar(6)]	[varchar(6)]	[varchar(6)]	Commented [CR9]: Should specify type of meal i.e., B=breakfast, L=lunch, D=dinner, S=snack

10.04	Physical Activity (in leisure time) in average			
	week	Days per week	Total time per day	
			Hour(s)	Minutes
	Vigorous	[<mark>pa_vigorous_days_per_week</mark>]	[pa_vigorous_total_hr]	[pa_vigorous_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Moderate	[pa_moderate_days_per_week]	[pa_moderate_total_hr]	[pa_moderate_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Mild	[pa_walking_days_per_week]	[pa_walking_total_hr]	[pa_walking_total_min]
	(Walking)	[int(11)]	[int(11)]	[int(11)]

12. EQ-5D - Data saved in "eq_5d.csv" and is in wide format

Place a tick in one box in each group below for the statement that best describes your own health state today.

12.01	Mobility	[I have no problems in walking about 1, I have some pro	blems in walking about 2,				
	[mobility_id] [int (11)] I am confined to bed 3]					
	1 I have no problems in walking about						
	2 I have some problems in walking about						
	3 🗆 I am confined t	o bed					
12.02	Self-Care	[I have no problems with self-care 1, I have some proble	ems with self-care 2,				
	[self_care_id] [int(1	1)] I am unable to wash or dress myself 3]					
	1 🗆 I have no probl	ems with self-care					
	2 I have some problems with self-care						
	3 🗆 I am unable to	wash or dress myself					
12.03	Usual Activities (e	.g. work, study, housework, family or leisure	activities)				
	[usual_activities] [in	t <mark>t(11)]</mark> [I have no problems with performing my usual activi	ties 1,				
		I have some problems with performing my usual act	ivities 2,				
		I am unable to perform my usual activities 3]					
	1 I have no problems with performing my usual activities						
	2 I have some problems with performing my usual activities						
	3 🗆 I am unable to	perform my usual activities					
CARRS	Translation Trial; Form I	E - Follow-up 12 monthly_All_ v1.4-3DEC2010	Page 4 of 23				

12.04 Pain/Discomfort

[pain_discomfort] [int(11)] [I have no pain or discomfort 1, I have moderate pain or discomfort 2, I have extreme pain or discomfort 3]

- 1 🗆 I have no pain or discomfort
- 2 🗆 I have moderate pain or discomfort
- 3 □ I have extreme pain or discomfort

12.05 Anxiety/Depression

[anxiety_depression] [int(11)] [I am not worried or depressed 1; I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]

- 1 🗆 I am not worried or depressed
- 2 \square I am moderately anxious or depressed
- 3 \square I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.



13. **Diabetes Treatment Satisfaction**

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale. How satisfied are you with your current treatment? 13.01 [current_treatment] [int] [0, 1, 2, 3, 4, 5, 6] Very satisfied Very dissatisfied 5[] 3[] 2[] 6[] 4[] 1[] 0[] 13.02 How often have you felt that your blood sugars have been unacceptability high recently? [blood_sugar_high] [int] [0, 1, 2, 3, 4, 5, 6] None of the time Most of the time 5[] 2[] 6[] 4[] 3[1 1[] 0[] How often have you felt that your blood sugars have been unacceptability low recently? 13.03 [blood_sugar_low] [int] [0, 1, 2, 3, 4, 5, 6] None of the time Most of the time 5[] 6[] 4[] 3[] 2[] 1[] 0[] How convenient have been finding your treatment to be recently? 13.04 [convienent_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very convenient Very inconvenient 6[] 5[] 4[] 3[] 2[] 1[] 0[] How flexible have you been finding your treatment to be recently? 13.05 [flexible_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very flexible Very inflexible 6[] 5[] 4[] 3[] 2[] 1[] 0[] 13.06 How satisfied are you with understanding of your diabetes? [understand_dibetes] [int] [0, 1, 2, 3, 4, 5, 6] Very dissatisfied Very satisfied 6[] 5[] 4[] 3[] 2[] 1[] 0[] 13.07 How satisfied would you be to continue with your present form of diabetes treatment? [present_dib_treat] [int] [0, 1, 2, 3, 4, 5, 6] Very satisfied Very dissatisfied 6[] 5[] 4[] 3[] 2[] 1[] 0[] 13.08 Would you recommend this form of treatment to someone else? [recommend_form] [int] [0, 1, 2, 3, 4, 5, 6] Yes, I would No, I would definitely definitely NOT recommend recommend this treatment this treatment 6[]

Health Utilities Index 14.

5[]

4[]

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

2[]

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

3[]

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 6 of 23

1[]

0[]

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] [1, 2, 3, 4]

- $1\square$ a. Able to see well enough without glasses or contact lenses
- 2□ b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses
- 4 d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] [1, 2, 3, 4]

- 1 a. Able to see well enough without glasses or contact lenses
- 2□ b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses
- 4 d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] [1, 2, 3, 4, 5]

- $1\square$ a. Able to hear what was said without a hearing aid
- 2D b. Able to hear what was said with a hearing aid
- $3\square$ c. Unable to hear what was said even with a hearing aid.
- $4\square\,$ d. Unable to hear what was said, but did not wear a hearing aid
- 5D e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room?

[other_person_conversation] [int] [1, 2, 3, 4, 5]

 $1 \square \$ a. Able to hear what was said without a hearing aid

 $2\square\,$ b. Able to hear what was said with a hearing aid

- $3\square$ c. Unable to hear what was said even with a hearing aid
- $4 \square \,$ d. Unable to hear what was said, but did not wear a hearing aid

 $5\square$ e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] [1, 2, 3, 4]

- $1\square\,$ a. Able to be understood completely
- 2 b. Able to be understood partially
- 3□ c. Unable to be understood
- 4□ d. Unable to speak at all

14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] [1, 2, 3, 4]

- 1 a. Able to be understood completely.
- 2□ b. Able to be understood partially.
- 3 c. Unable to be understood.
- 4□ d. Unable to speak at all.

14.07. Which one of the following best describes how you have been feeling during the past 4 weeks? [feeling] [int] [1, 2, 3, 4, 5]

- 1 a. Happy and interested in life
- 2□ b. somewhat happy
- 3□ c. somewhat unhappy
- 4□ d. Very unhappy
- 5□ e. So unhappy that life was not worthwhile
- 14.08. Which one of the following best describes the pain and discomfort you have experienced during

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 7 of 23

the past 4 weeks?

[discomfort_exp] [int] [1, 2, 3, 4, 5]

 $1\square$ a. Free of pain and discomfort

 $2\Box$ b. Mild to moderate pain or discomfort that prevented no activities.

3 c. Moderate pain or discomfort that prevented a few activities

4 d. Moderate to severe pain or discomfort that prevented some activities

5 e. severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] [1, 2, 3, 4, 5, 6]

1 a. Able to walk around the neighborhood without difficulty, and without walking equipment

2 b. Able to walk around the neighborhood with difficulty; but did not require walking equipment

or the help of another person

 $3\square$ c. Able to walk around the neighborhood with walking equipment, but without the help of another person $4\square$ d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood

 $5\square$ e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood

6□ f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.) [hands_finger] [int] [1, 2, 3, 4, 5, 6]

1□ a. Full use of hands and ten fingers

2 b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person

 $3\square$ c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)

4 d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)

5 - E. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools)

6 f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] [1, 2, 3, 4]

 $1\square$ a. Able to remember most things

2□ b. Somewhat forgetful

3□ c. Very forgetful

4 d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] [1, 2, 3, 4, 5]

 $1\square$ a. Able to think clearly and solve day to day problems

- $2\square$ b. Had a little difficulty when trying to think and solve day to day problems
- $3\square$ c. Had some difficulty when trying to think and solve day to day problems

 $4\square$ d. Had great difficulty when trying to think and solve day to day problems

5 e. Unable to think or solve day to day problems

14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] [1, 2, 3, 4]

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 8 of 23

- 1 a. Eat, bathe, dress and use the toilet normally
- 2 b. Eat, bathe, dress and use the toilet independently with difficulty
- 3 c. Required mechanical equipment to eat, bathe, dress or use the toilet independently
- 4 d. Required the help or another person to eat, bathe, dress or use the toilet
- 14.14. Which one of the following best describes how you have been feeling during the past 4 weeks? [feeling_health_utility] [int] [1, 2, 3, 4]
- 1 a. Generally happy and free from worry
- 2D b. occasionally fretful, angry, irritable, anxious or depressed
- 3 c. often fretful, angry, irritable, anxious or depressed
- 4 d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

[discomfort_health_utility] [int] [1, 2, 3, 4, 5]

1 a. Free of pain and discomfort

2 b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities

3 c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities

4 d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief

5 e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15&16. Frequency & Costs of Care

Please respond to the following questions regarding outpatient care you received in the previous 12 months. Outpatient care is all instances of clinic visits that did not necessitate hospitalization. (Exclude current visit)

		Indicate	Month of last visit/test/exa	m
15.01	Clinic Visits	number	(MMM/yyyy)	[]unknown
	[fpc_clinic_visit_indicate_no] [int(11)] [fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] [-1]			
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] [-1]		/	[]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)]		/	[]unknown
15.04	[fpc_cholestrol_testing_unknown] [int(11)] [-1] Foot Exam at clinic		1	[]unknown
15.04	[fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] [-1]			[Junkhown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] [-1]		/	[]unknown
15.06	Microalbuminuria check		/	[]unknown

Commented [r10]: The day (DD) for the below listed variables are correct and are auto generated by the system and therefore the date is in DD-MMM-YY format: [fpc_clinic_visit_month_of_visit] [fpc_hba_testing_month_of_visit]

- [fpc_cholestrol_testing_month_of_visit] [fpc_foot_exam_unknown]
- fpc eve exam month of visit
- [fpc_etye_exam__noninn_of_visit] [fpc_microal_check_month_of_visit] [fpc_etye_month_of_visit] [fpc_dental_exam_month_of_visit] [fpc_dietician_visit_month_of_visit]

Commented [CR11]: For Q.Nos. 15.01 - 15.09, specify Indicate number, Month of last visit & unknow If response is [unknown] data is saved as '-1'

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 9 of 23

	[fpc_microal_check_indicate_no] [int(11)]		
	[fpc_microal_check_month_of_visit] [varchar(15)]		
	[fpc_microal_check_unknown] [int(11)] [-1]		
15.07	ECG	/	[]unknown
	[fpc_ecg_indicate_no] [int(11)]		
	[fpc_ecg_month_of_visit] [varchar(15)]		
	[fpc_ecg_exam_unknown] [int(11)] [-1]		
15.08	Dental Exam	/	[]unknown
	[fpc_dental_exam_indicate_no] [int(11)]		
	[fpc_dental_exam_month_of_visit] [varchar(15)]		
	[fpc_dental_exam_unknown] [int(11)] [-1]		
15.09	Dietician/Diabetes Education	/	[]unknown
	[fpc_dietician_visit_indicate_no] [int(11)]		
	[fpc_dietician_visit_month_of_visit] [varchar(15)]		
	[fpc_dietician_visit_unknown] [int(11)] [-1]		

16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR:



OUTPATIENT CARE

Please respond to the following questions regarding outpatient care you received for diabetes in the previous **1** year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization. **EXCLUDE current visit**.

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1 year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.

LYOLU					
16.02	0.02 How many outpatient visits did you make in the past 1 year (exclude current visit)?				
	[out_patient_visit] [int(11)]				
16.03	How many days, including half days, did you miss from work				
for outpatient visits in the past 1 year?days [] N/A					

[days_miss_work] [int(11)] [days_miss_work_na] [int(11)] [1]

16.04 List all persons who accompanied you to outpatient visits in the past 1 year:

	Person Relation (e.g. father)	Occupation (number*)	Monthly salary	Number visits accompanied				
-								

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 10 of 23

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item	Number	Average cost
		of times	One-time (Rupees)
16.05	Consultation Fee		
	[con_fee_frq] [int(11)] [avg_con_fee] [double]		
16.06	Lab Tests (HbA1c, blood glucose, urine check)		
	[lab_test_frq] [int(11)] [avg_lab_test] [double]		
16.05	Eye Exam		
	[eye_eam_frq] [int(11)] [avg_eye_exam] [double]		
16.06	ECG		
	[ecg_frq] [int(11)] [avg_ecg_fee] [double]		
16.07	Medicines (tablets, insulin)		
	[med_frq] [int(11)] [avg_med_fee] [double]		
16.08	Supplies (including glucose strips, gauze, sterile solution, etc.)		
	[supply_frq] [int(11)] [avg_supply_fee] [double]		
16.09	Transportation		
	[transport_frq] [int(11)] [avg_transport] [double]		
16.10	Food (personal)		
	[food_personal_frq] [int(11)] [avg_food_personal] [double]		
16.11	Additional cost for escort(s) (e.g. food)		
	[escorts_freq] [int(11)] [avg_escorts] [double]		
16.12	Other out-of-pocket expenses		
	[outpocket_frq] [int(11)] [avg_outpocket_exp] [double]		

Commented [CR12]: For Q.no 16.05 to 16.12 [frq] indicates "Number of times" & [avg] indicates "Average cost"

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetes-related complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year?

times [hospital_emergency] [int(11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below - (Make sure that visits listed below equals total number listed in 16.13) When providing time, include half-days.

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 11 of 23

	TYPE 1= Hospitalization, NO	Days of stay	Hospital Cost including	Transportation Cost, including	Food Cost	Additional Escort(s)				
	surgery 2= Surgery 3= Emergency Room		medicine/ supplies (total stay)	ambulance fees (total stay)		Cost	Relation	Occupation (number*)	Monthly Salary	Days accompanied
1										
2										
3										
4										
5										
6										

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

18. Signature of Care Coordinator/Research Officer

Signature:

18.01Name:

Instructions for Continuation (after completion of Form E Part 1)

[] Attach Reports of ECG and Form G-Eye Exam.

[] Control Group: Take participant to STUDY PHYSICIAN to complete PART 2 of Form E. After completion, enter Form E Parts 1 & 2 into eCRF. Include all source documents in patient's trial folder.

[] Intervention Group:

- (1) Enter Form E Sections 1-4 into EHR-DSS (including update of contact information)
- (2) Review patient medications. Update medication changes in writing on Form Z.
- (3) Provide paper Form Z (with medication update) and rest of Form E Part 2 to STUDY PHYSICIAN during consultation with participant.
- (4) Attach completed Form Z to this Form E. Update patient with information.
- (5) After patient leaves, enter Form Z and rest of Form E in eCRF.
- (6) Include all source documents in patient's trial folder.

PART 2: complete by STUDY PHYSICIAN

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 13 of 23

2. ECG and Eye Exam

<u>May use results within past 1 month</u> for ECG and Form G-Eye Exam (attach to end of this form). Otherwise, attempt to complete TODAY, or ensure that <u>testing is done within 2 weeks of today's date</u>. Update in paper and eCRF as soon as available. Retain copies of ECG and eye exam results as source documents.

ECG:

2.01	ECG Date:// [s_ec	g_date]	[date]				
	not available form within past month. Scheduled today. update below once results available.						
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] [Yes 1, No 2]	1[]Y	→ [] new or worsened [] unchanged or improved	2[] N			
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] [Yes 1, No 2]	1[]Y	→ [] new or worsened [] unchanged or improved	2[]N			
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] [Yes 1, No 2]	1[] Y	→ [] new or worsened [] unchanged or improved	2[] N			
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] [Yes 1, No 2]	1[] Y	 → [] new or worsened [] unchanged or improve 	2[] N			

Commented [CR13]: This option is added in CRF

Commented [CR14]: Options (new or worsened & unchanged or improved) are not present at both front-end and back-end for Q.Nos 2.02 to 2.05

EYE EXAM:

May use results from past 1 month.

[] Attach <u>Form G-Eye Exam</u> to end of this Form E – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

12. Complications Update

In the past year, since the last baseline/annual visit, has the patient had any of the following:

	no/unsure	Yes, <u>number</u>		
New/Worsening Blindness in either eye thought to be due to diabetes				Form X
[h_eyes_blindbess] [int(11)] [no/unsure 0, Right 1, Left 2, Both 3]	[]	[]R	[]L	
New/Worsening Glaucoma				
[h_eyes_glaucoma] [int(11)]	[]	[]R	[]L	
[no/unsure 0,Right 1, Left 2, Both 3]				
New/Worsening Cataract				
[h_eyes_cataract] [int(11)]	[]	[]R	[]L	
[no/unsure 0,Right 1, Left 2, Both 3]				
Cataract Surgery				Form X
[h_eyes_cataract_surgery] [int(11)]	[]	[]R	[]L	
[no/unsure 0,Right 1, Left 2, Both 3]				
Laser photocoagulation therapy		[eye_laser_therep	y_lft]	Form X
[<mark>h_eyes_laser_therapy]</mark> [no/unsure -1, Yes 1]	[]	[Right 1, Left 2] [] R,		

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 14 of 23

		[eye_laser_therepy_rgt_no] [] L, [eye_laser_therepy_lft] [eye_laser_therepy_lft_no]	
Other eye therapy	r 1	[], specify:	Form X
[h_eyes_other_therapy] [1 Yes,-1 No]	1 1	[h_eyes_other_therapy_spcify]	

In the past year, since the last baseline/annual visit, has the patient had any of the following:

in the past year, since the last baseline/annual visi		no/			
		unsure	Yes, <u>number</u>		
1.11 ACS: Myocardial Infarction or Unstable Angi	ina			Form X	
[h_cardiovascular_acs] [int(11)] [no/unsure -1	1, Yes 1]	[]	[]		
[if Yes 1] → [acs_num] [int(11)]					Commented [CR15]: If the response for "h_cardiovascular
.12 Angioplasty (PCI) /Open-heart surgery (CAB	G)			Form X	is [Yes 1] specify Number
[h_cardiovascular_pci_cabg] [int(11)] [no/uns	sure -1, Yes 1]	[]	[]		
[if Yes 1] → [pci_num] [int(11)]		<u> </u>	<u> </u>		Commented [CR16]: If the response for
.13 New/Worsened Stable Angina				Form X	"h_cardiovascular_pci_cabg" is [Yes 1] specify Number
[stable_angina] [int(11)] [no/unsure -1, Yes 1]		[]	[]		
.14 Stroke (Ischemic or Hemorrhagic) or TIA				Form X	
[h_cardiovascular_stroke_tia] [int(11)] [no/uns	sure -1, Yes 1]	[]	[]		
[if Yes 1] → [stroke_num] [int(11)]			<u> </u>		Commented [CR17]: If the response for
.15 New/Worsened Arrhythmia (requiring med in	itervention)			Form X	"h_cardiovascular_stroke_tia" is [Yes 1] specify Number
[h_cardiovascular_arrtythmia] [int(11)] [no/un	isure -1, Yes 1]	[]	[]		
.16 New/Worsened Heart Failure				[] if hosp/ER	
[h_cardiovascular_heart_attack] [int(11)] [no.	/unsure -1, Yes 1]	[]	[]	– Form X	
.28 New/Worsened Neuropathy – hands/feet					
[h_other_neuropathy_hands_feet] [int(11)] [/	no/unsure -1, Yes 1]	[]	[]		
.29 New/Worsened Neuropathy - sexual:erectile	e dysfunction				
[h_other_neuropathy_sexual] [int(11)] [no/uns	sure -1, Yes 1]	[]	[]		
New Amputation				Form X	
[foot_ampu_yesno] [int(11)] [no/unsure -1, Yes	s 1]	[]	[]		
[if Yes 1] → [foot_ampu_num] [int(11)]					Commented [CR18]: If the response for "foot_ampu_yesn
.18 Peripheral revascularization (angioplasty/ su	irgery)			Form X	[Yes 1] specify Number
[h_peripheral_surgery] [int(11)] [no/unsure -1,		[]	[]		
[if Yes 1] → [h_peripheral_surgery_year]	archar(11)]	L	<u> </u>		Commented [CR19]: If the response for "h_peripheral_su
.19 Chronic leg/foot ulcer (6 weeks or more) – in	clude current			[] if hosp/ER	is [Yes 1] specify Number
[h_peripheral_foot_ulcer] [int(11)] [no/unsure	-	[]	[]	– Form X	
[if Yes $1 \rightarrow [h_{peripheral_foot_ulcer_year]}$	[varchar(11)]				Commented [CR20]: If the response for
.43 Other Major Infection (hospitalization)		[]	[]	Form X	"h_peripheral_foot_ulcer" is [Yes 1] specify Number
[oth_maj_infec_yesno] [int(11)] [no/unsure -1	1, Yes 1]				
ARRS Translation Trial; Form E – Follow-up 12 monthly_All_	v1.4-3DEC2010	P	age 15 of 23	3	

	[if Yes 1] → [oth_maj_infec_num] [int(11)]			-	Commented [CR21]: If the response for "oth_maj_infec_yes is [Yes 1] specify Number
1.44	Minor Infection (NO hospitalization)	[]	[]		
	[maj_inf_yesno] [int(11)] [no/unsure -1, Yes 1]				
	[if Yes 1] → [maj_inf_num] [int(11)]				Commented [CR22]: If the response for "maj_inf_yesno" is [Yes 1] specify Number
1.33	New/Worsened Asthma [h_other_asthma] [int(11)] [no/unsure -1, Yes 1]	[]	[]	[] if hosp/ER – Form X	
1.34	New/Worsened COPD (Chronic Bronchitis, Emphysema) [h_other_copd] [int(11)] [no/unsure -1, Yes 1] [int(11)]	[]	[]	[] if hosp/ER – Form X	
1.35	New/Worsened Liver disease [h_other_liver_disease] [int(11)] [no/unsure -1, Yes 1]	[]	[]	[] if hosp/ER – Form X	
1.36	New/Worsened Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] [no/unsure -1, Yes 1]	[]	[]	[] if hosp/ER – Form X	
1.37	New/Worsened Hip Fracture/Replacement [h_other_hip_facture] [int(11)] [no/unsure -1, Yes 1]	[]	[]	Form X	
1.38	New/Worsened Depression [h_other_depression] [int(11)] [no/unsure -1, Yes 1]	[]	[]	[] if hosp/ER – Form X	
1.39	Severe HYPOglycemia (hospitalization/ER) [sever_hypoglycemia] [int(11)] [no/unsure -1, Yes 1] [if Yes 1] → [sever_hypoglycemia_num] [int(11)]	[]	[]	Form X	Commented [CR23]: If the response for "sever hypoglycen
	Mild HYPOglycemia [mild_hypoglycemia] [int(11)] [no/unsure -1, Yes 1]	[]	[]		is [Yes 1] specify Number
	[if Yes $1 \rightarrow [mild_hypoglycemia_num] [int(11)]$				Commented [CR24]: Need to check, This variable "mild hypoglycemia" is not seen in front-end
1.40	Other hospitalization for Diabetes	[]	[]	Form X	But present in back-end If the response for "mild_hypoglycemia" is [Yes 1] specify Num
1.41	Other major health condition(s), hospitalizations, emergency room visits not listed above, specify:	[]	[]	Form X	
	[oth_maj_health_cond] [int(11)] [no/unsure -1, Yes 1]				Commented [CR25]: If the response is [If Yes 1] no. of tim not found
1.42	Total Number of Hospitalizations/emergency room visits from p [no_of_time_hospitaiz] [int(11)]	oast year			

Complete a Form X for all SAE events listed above. For each hospitalization/emergency room visit, document in source notes, when, where and why it was made. If available, include discharge summary as source document.

In the past year, since the last baseline/annual visit, has the patient had any of the following:

1.43	Out of ordinary severe muscle aches/pains		[]N	[] V Obtain CBK			
	[outof_ordinary_musclespain] [int(11)] [Yes 1, No 2	<pre>usclespain] [int(11)] [Yes 1, No 2]</pre>		[] Y, Obtain CPK			
1.44	Medication side effects (i.e. cough from Ace-I, alle	ergic reaction)			11/		
	[medic_side_effect] [int(11)] [Yes 1, No 2]		[]N	L]Y		
3.	B. Foot Exam						
		Right Foot		Lef	t Foot		
3.01	Amputation	[] N/A		[]	N/A		
	[fe_amputation_right_foot]	[] toe [] ray (metatarsal) [] forefoot		[] toe			
	[int(11)]			[] ray (metatarsal) [] forefoot			
	[fe_amputation_left_foot]						
	[int(11)] [] foot				oot		
	[N/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5,	[] below the knee		[] below the knee			
	below knee 6, above knee 7]	[] above the k	nee	[]a	above the knee		
3.02	Appearance	1[] normal		1[]	normal		
	[fe_appearance_right_foot_normal]	2[] abnormal	, check	2[]	abnormal, check		
CARRST	ARRS Translation Trial: Form F - Follow-up 12 monthly All v1430FC2010 Page 16 of 23						

Commented [CR26]: If the response is [abnormal 2] specify below mentioned options 1 to 7 (check all that apply) for right foot & left foot

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 16 of 23

	[int(11)] [normal 1, abnormal 2]		all that a		all that ap	
	[fe_appearance_left_foot_normal]		1[](deformities	1[]d	eformities
	[int(11)] [normal 1, abnormal 2]	[4]	2[] dry skin/f	dystrophic nails; fissure	2[] dy dry skin/fis	vstrophic nails; ssure
	[fe_appearance_right_foot_deformities] [int(11)] [fe_appearance_right_foot_dystrophic] [int(11)] [3[](callus	3[] ca	allus
	[fe_appearance_right_foot_callus] [int(11)] [3]	~]	4[]	ulceration	4[]ul	ceration
	[fe_appearance_right_foot_unceration] [int(11)]	[4]	5[]i	nfection	5[] in	fection
	[fe_appearance_right_foot_infection] [int(11)] [5]			discoloration		scoloration
	[fe_appearance_right_foot_dys] [int(11)] [6]			other:	7[] of	
	[fe_appearance_right_foot_other] [int(11)] [7]					
	[fe_appearance_right_foot_otherd] [varchar(200)] [other specify]					
3.03	Posterior tibial pulse		1[]Y	2[]N	1[]Y	2[] N
	[fe_posterior_right_foot] [int(11)] [Yes 1, N	Vo 21				
	[fe_posterior_left_foot] [int(11)] [Yes 1, No					
3.04	Doraslis pedis pulse		1[]Y	2[]N	1[]Y	2[]N
	[fe_doraslis_right_foot] [int(11)] [Yes 1, No [fe_doraslis_left_foot] [int(11)] [Yes 1, No					
3.05	Pre-tibial EDEMA today		[]none		[] none	
	[fe_pre_tibial_edema_right_foot] [int(11)]	[]up to		[] up to a	ankle
	[fe_pre_tibial_edema_left_foot] [int(11)] [None 0, up to ankle 1,between ankle & mid-calf	I	[] between ankle & mid-calf		[] between ankle & mid- calf	
	between mid-calf & knee 3]	2,	[] betv knee	veen mid-calf &	[] betwe knee	en mid-calf &
3.06	Ankle Reflex		1[]	2[] N	1[]Y	2[] N
	[fe_ankle_relax_right_foot] [int(11)] [Yes 1, No 2]		Y			
	[fe_ankle_relax_left_foot] [int(11)] [Yes 1, No 2]					
3.07	Knee Reflex		1[]	2[]N	1[]Y	2[] N
	[fe_knee_reflax_right_foot] [int(11)]		Y			
	[Yes 1, No 2]					
	[fe_knee_reflax_left_foot] [int(11)] [Yes 1, No 2]					
3.08	Vibration, tuning fork (perception at grea	at toe)	[]prese	ent (≥10 sec)	[] present	: (≥10 sec)
	[fe_vibration_right_foot] [int(11)]		[] redu	ced (<10 sec)	[] reduced (<10 sec)	
	[fe_vibration_left_foot] [int(11)]		[]abse	nt	[] absent	
	[present (≥10 sec) 1, reduced (<10 sec) 2, abser	nt 3]				
3.09	10g Monofilament		[]prese	ent (≥8)	[] present	: (≥8)
	(number applications detected)			ced (1-7)	[] reduced (1-7)	
	[fe_monofilament_right_foot] [int(11)]		[]abse	. ,	[]absent	. ,
	[fe_monofilament_left_foot] [int(11)]					
	[present (≥8) 1, reduced (1-7) 2, absent 3]					
	Assessment					
0.40	Deformities	1[]Y ->		or worsened		2[]N
3.10	[fe_participant_has] [varchar(20)]			nanged or impro	oved	
3.10	[fe_participant_has] [varchar(20)]	[assm_amputation_newunch] [int(11)]				
3.10	[te_participant_has] [varchar(20)] [Yes 1, No -1]					
	[Yes 1, No -1]	[new or wors	sened 1, un	changed or improve	d 0]	01.1 N
3.10 3.11		[new or wors	sened 1, un ▶[]new		ed 0]	2[] N

 [fe_appearance_left_foot_deformities] [int(11)]
 [1]

 [fe_appearance_left_foot_callus] [int(11)]
 [2]

 [fe_appearance_left_foot_callus] [int(11)]
 [3]

 [fe_appearance_left_foot_unceration] [int(11)]
 [4]

 [fe_appearance_left_foot_dys] [int(11)]
 [6]

 [fe_appearance_left_foot_dys] [int(11)]
 [6]

 [fe_appearance_left_foot_other] [int(11)]
 [7]

 [fe_appearance_left_foot_other_d]
 [varchar(200)] [other specify]

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 17 of 23

Commented [CR27]: Q.no.3.10 has multiple responses, and data stored in this column as string so we are splitting & re naming the categories as [1,-1, 2,-2, 3,-3, 4,-4]

Commented [CR28]: Doubt about the naming convention of this variable but based on values, taken as [assm_amputation_newunch]

Q.no.4.01 to
2.no.4.01 to
2.no.4.01 to
2.no.4.01 to
2.no.4.01 to
Q.no.4.01 to
Q.no.4.01 to
Q.no.4.01 to
Q.no.4.01 to
).no.5.01 to
Q.no.5.01 to

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 18 of 23

If any	If any 5.01-5.03 is YES, complete below.						
	Muscles	Right	Left				
5.04	ARMS-Tone [ne_arms_tone_right] [int(11)] [ne_arms_tone_left] [int(11)] [normal 1, flaccid 2, rigid/spastic 3]	[]normal []flaccid []rigid/spastic	[] normal [] flaccid [] rigid/spastic				
5.05	ARMS-Strength [ne_arms_strengt_right] [int(11)] [ne_arms_strengt_left] [int(11)] [normal 1, deficit 2]	[]normal []deficit	[]normal []deficit				
5.06	LEGS-Tone [ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)] [normal 1, flaccid 2, rigid/spastic 3]	[] normal [] flaccid [] rigid/spastic	[] normal [] flaccid [] rigid/spastic				
5.07	LEGS-Strength [ne_legs_strength_right] [int(11)] [ne_legs_strength_left] [int(11)] [normal 1, deficit 2]	[]normal []deficit	[]normal []deficit				
	Reflexes	Right	Left				
5.08	Biceps [ne_reflexes_biceps_right] [int(11)] [ne_reflexes_biceps_left] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent				
5.09	Triceps [ne_reflexes_triceps_right] [int(11)] [ne_reflexes_triceps_left] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent				
5.10	Knee [ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent				
5.11	Ankle [ne_reflexes_ankle_right] [int(11)] [ne_reflexes_ankle_left] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent				
5.12	[ne_old_deficit] [int(11)]	→ [] new or worsened [] unchanged or improve deficit_newunch] [int(11)]	2[] N				

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 19 of 23

FORM E – Follow-up 12 monthly		Participant ID:
CARRS Translation Trial	Participant Name:	Initials:
Complete by CC, RO, and SP	Date of Visit (do	l/MMM/yyyy): / / /

6. MEDICATIONS and MANAGEMENT

6.01	Drug Allergies [other_drug_allergies] [ir	nt(11)]	[]no/unknown [] yes, specify any changes since baseline: [if Yes 1] → [drug_allergies] [varchar(20)]		e baseline:	
	[Ves 1, No 2, unknown -1]					
6.02	MEDICATIONS - CONT				ITERVENTION	GROUP
^For (1)	Below, list all medications that the participant is presently taking <i>on a regular basis currently</i> ^For (1) Insulin, (2) OHAs, and (3) Blood pressure/lipid-lowering/blood-thinner <u>MIXED medications</u> , describe all constituents separately under "Generic Name" and "Single Dose"					
_	Brand Name	Ga	[^] List ALL consti Insulin, OHAs, I neric Name	BP meds	Frequency	Total daily dose
Туре	[name] [varchar(200)]	[generic_ [varchar	_name]	Single Dose [single_dose] [double]	[frequency] [double	[total_daily_ dose] [double]
Insulin						
OHAs						
BP						
Lipid-						
lowerin						
g						

Commented [CR32]: If the response is [Yes 1] specify the changes since baseline

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 20 of 23

	anslation Trial by CC, RO, and SP	Participant Name: Date of			
	by 00, 10, 10, 110 01	Date of Visit (dd/MMM/yyyy): /			/
Blood- thinner					
Туре	Brand Name	Generic Name	Single Dose	Frequency	Total daily dose
Other					

CONTROL GROUP: Review Form E with Principal Investigator/Co-Investigator. Have PI/Co-I make any changes to medications above. Strike out old medications and write in changed/new medications. Make sure final medication list is obvious and legible. Attach prescription with updated medications as source document.

→ COMPLETE BELOW FOR CONTROL AND INTERVENTION PARTICIPANTS.

6.03		Management of diabetes in last 6 months [dibetes_mgt] [varchar(50)]	[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1 Biquanide (Metformin) 2
	[]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)	Thazolidineodione (Pioglitazone) 3
	[]	Biguanide (Metformin)	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)4
	[]	Thazolidineodione (Pioglitazone)	Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
	[]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)	Lispro, Aspart, Glulisine insulins (rapid-acting) 6
	[]	Glinide (Nateglinide, Repaglinide, Mitiglinide)	Regular Insulins (short-acting) 7
	[]	Lispro, Aspart, Glulisine insulins (rapid-acting)	NPH or Lente Insulins (intermediate-acting) 8 Glargine or Determir Insulins (very long-acting) 9
	[]	Regular Insulins (short-acting)	Other diabetic treatment 10
	[]	NPH or Lente Insulins (intermediate-acting)	Dietician or Educator referral 11
	[]	Glargine or Determir Insulins (very long-acting)	Weight control or exercise program 12
		1	Home blood glucose monitoring 13

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 21 of 23

FORM E – Follow-up 12 r	monthly Participant I	D:	
CARRS Translation Trial	Participant Name:	Initials:	
Complete by CC, RO, and S	SP Date of Visit (dd/MMM/yyyy): /	/	
[] Other dia	abetic treatment		
	or Educator referral		
	control or exercise program		
	lood glucose monitoring		
	edications		
	ibetes_mgt] [varchar(100)]		
	e or thiazide-like diuretic		Fhaizide or thiazide-like diuretic 1
[] Other dit			Dther diuretic 2
[] ACE inhi		A	ACE inhibitor 3
	nsin 2 receptor antagonist (ARB)	/	Angiotensin 2 receptor antagonist (ARB) 4
[] Angioter			Beta-blocker 5
			Calcium channel blocker (CCB) 6
	channel blocker (CCB)		Other antihypertensive agent 7
	ntihypertensive agent		Statin 8 Dther cholesterol lowering drug 9
[] Statin			Aspirin 10
	nolesterol lowering drug		Other anti-platelet agent 11
[] Aspirin			Dral anticoagulant 12
[] Other an	nti-platelet agent	1	Vitrates (NOT sublingual) 13
[] Oral anti	icoagulant		formone replacement therapy 14
[] Nitrates	(NOT sublingual)		Thyroid Agents 15
[] Hormone	e replacement therapy		Dral/inhaled steroids 16 Dral asthma drugs (exclude steroids) 17
[] Thyroid	Agents		Antidepressant 18
[] Oral/inha	aled steroids		Anti-neuropathy medications (gabapentin, pregabalin,
[] Oral asth	hma drugs (exclude steroids)		amatryptiline) 19
[] Antidepr	essant		Erectile Dysfunction drug 20
	ropathy medications (gabapentin, pregabalin, amatryptilir	a)	Herbal/alternative medicine 21 /itamins/nutritional supplements 22
	Dysfunction drug		Dther, not listed above 23
	Iternative medicine		· · · · · · · · · · · · · · · · · · ·
	s/nutritional supplements		
	ot listed above		

8. Signature of Physician

8.01	Name:		Signature:
8.02	Date Signed: /	/	
8.05			
	Control Group: Date o	f Next Participant Visit: _	//
	Intervention Group:	Study physician review	s and completes Form Z (Management Plan).

Date to be listed in Form Z management plan by physician.

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 22 of 23

FORM E – Follow-up 12 month	ly	Participant ID:
CARRS Translation Trial	Participant Name:	Initials:
Complete by CC, RO, and SP	Date of Visit (dd/l	MMM/yyyy): / / /

Page 23 of 23

FORM F - Close-out_All

CARRS Translation Trial

- All dates dd/MMM/yyyy (e.g. 31/DEC/2010)
- Place cross [X] in the appropriate boxes. Write number in spaces (f none, write 0)
 See Form Completion Notes, for definitions and explanations
- Store copies of available source documents (SD), where indicated, in patient's trial folder

PART 1: To be completed by CARE COORDINATOR or RESEARCH OFFICER			
Data entry by:	Screening ID: S		
[data_entry_by] [varchar (100)]			
Initials	Participant ID:		
DATE entered: / /	[participant_id] [varchar (20)]		
	Date of Visit (dd/MMM/yyyy): / / / /		
	[date of visit] [date]		

FORM E – Data saved in "patient_forme.csv" and is in wide format

1. lı	1. Intake					
A1.01	Complaints/Update:					
	[complaints] [varchar(500)]					
1.02-1.0	1.02-1.04 For intervention group/care coordinator only:					
A1.02	Number of severe hypoglycemic episodes since last visit (If present, complete Form X)					
	[severe_hg_count] [int(11)]					
A1.03	Number of mild hypoglycemic episodes since last visit					
	[mild_hg_count] [int(11)]					
A1.04	Other SAE since last visit (If present, complete Form X with investigator)	[]Y	[]N			
	[other_sae] Yes=1, No=0					

2. Measures

B1.02	Heart rate	(beats/min)
	[heart_rate] [int(11)]	
B1.03	Blood pressure 2 nd reading	/ (mmHg)
	[blood_pressure_h_1] [int(11)] / [blood_pressure_l_1] [int(11)]	
B1.04	Blood pressure 3 rd reading	/ (mmHg)
	[blood_pressure_h_2] [int(11)] / [blood_pressure_l_2] [int(11)]	
B1.06	Waist circumference	(cm)
	[waist_circumference] [double]	
B1.07	Weight	(kg)
	[weight] [double]	

Investigations 3.

B2.04	Hemoglobin A1c	%	Date: / / /
	[hemoglobin_a1c] [double]		[hemoglobin_a1c_date] [date]
B2.10	Fasting blood glucose (venous)	(mg/dL)	Date: / / /
	[fasting_blood_glucose_mgdl] [double]		[fasting_blood_glucose_date] [date]
B2.13	Post-prandial blood glucose (venous) – optional	(mg/dL)	Date:/ / [post_prandial_blood_glu_date] [date]
	[post_prandial_blood_glu] [double]		
B2.05	ALT – optional	(units/L)	Date: / / /
	[alt] [double]		[alt_date] [date]

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 1 of 23

		1	
A2.06	Total Cholesterol	(mg/dL)	Date: / / /
	[total_cholesterol] [double]		[total_cholesterol_date] [date]
B2.07	HDL Cholesterol	(mg/dL)	Date: / / /
	[hdl_cholesterol] [double]		[hdl_cholesterol_date] [date]
B2.08	LDL Cholesterol (indirect)	(mg/dL)	Date: / / /
	[Idl_cholesterol] [double]		[Idl_cholesterol_date] [date]
B2.09	Triglycerides	(mg/dL)	Date: / / /
	[triglycerides] [double]		[triglycerides_date] [date]
B2.02	Sodium – optional	(mEq/L)	Date: / / /
	[sodium] [double]		[sodium_date] [date]
B2.03	Potassium – optional	(mEq/L)	Date: / / /
	[potassium] [double]		[potassium_date] [date]
B2.01	Creatinine		Date: / / /
	[creatinine_mg] [double]	(mg/dL)	[creatinine_date] [date]
B2.12	Albumin:creatinine ratio	·	Date:/ / /
	[s_albumin_mg] [double]	(mg/g)	[s_albumin_date] [date]

11. Self-Care - Data saved in "patient_selfcare_e.csv" &"patient_selfcare_form_e.csv" and is in long format

The questions below ask you about your diabetes self-care activities <u>during the past 7 days</u>. If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET									
11.01	On average, over the past month, how many DAYS PER WEEK have you followed your diet plan? [self_care_id=2] [int(11)] [0 1 2 3 4 5 6 7]	0	1	2	3	4	5	6	7
11.02	On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables? [self_care_id=3] [int(11)] [0 1 2 3 4 5 6 7]	0	1	2	3	4	5	6	7
11.03	On how many of the last SEVEN DAYS did you eat high fat foods such as fried items or full-fat dairy products? [self_care_id=4] [int(11)] [0 1 2 3 4 5 6 7]	0	1	2	3	4	5	6	7
11.04	On how many of the last SEVEN DAYS did you space eating meals evenly through the day? [self_care_id=5] [int(11)] [0 1 2 3 4 5 6 7]	0	1	2	3	4	5	6	7
EXERCISE									
11.05	On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Total minutes of continuous activity, including walking)	0	1	2	3	4	5	6	7
11.06	[self_care_id=6] [int(11)] [0 1 2 3 4 5 6 7] On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work? [self_care_id=7] [int(11)] [0 1 2 3 4 5 6 7]	0	1	2	3	4	5	6	7
BLOOD SUGAR TESTING									
11.07	Are you testing your blood sugar as recommended by your health care provider? [self_care_id=9] [int(11)] [Yes 1, No 0, N/A -1]	-] No] Ye		2[]]	N/A (:	skip t	o 11.	09)

Commented [CR1]: In Self-care section, data is saved in 2 files 1. "patient_self_care_e.csv "& 2." patient_selfcare_form_e.csv and unique ID is "self_care_id "

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 2 of 23
11.08	On how many of the last SEVEN DAYS did you test your blo sugar? [self_care_id=8] [int(11)] [0 1 2 3 4 5 6 7]	bod 0 1 2 3 4 5 6 7
	ATIONS	
11.09	On how many of the last SEVEN DAYS, did you take you recommended <u>diabetes medication</u> ? (pills and/or insulin	
	[self_care_id=10] [int(11)] [0 1 2 3 4 5 6 7]	
FOOT	CARE	
11.10	On how many of the last SEVEN DAYS did you check your feet? [self_care_id=11] [int(11)] [0 1 2 3 4 5 6 7]	0 1 2 3 4 5 6 7
TOBAC	· · · · ·	
11.11	[self_care_id=12] [int(11)] [never 0, quit 1, Yes 2] 1 [[if quit 1] → [quit_smoking_year] [varchar(20)]] Never] Quit:/ (MMM/yyyy)] Yes, # smoked per day: Commented [CR2]: If the response is [quit 1] specify the year response is [yes 2] specify no. smoked per day
11.12	[self_care_id=13] [int(11)] [never 0, quit 1, Yes 2] 1 [] No] Quit / (MMM/yyyy)] Yes, # packets per day: Commented [CR3]: If the response is [quit 1] specify the year response is [yes 2] specify no. packet per day
11.13] No] Yes 2 [] N/A
ALCOH	OL	
11.14	Drink alcohol regularly? (at least once a week for most we in past year) One drink: wine=100 ml, spirit=30 ml, beer=330 ml [self_care_id=15] [int(11)] [never 0, Yes 1] [if yes 1] → [drink_per_day] [int(11)]	1 [] Yes, # drinks per day: Commented [CR4]: If the response is [yes 1] specify no. dr
STRES	S	per day
11.15	How often do you feel stress (from work, responsibilities [] daily [] few times a week [] [self_care_id=16] [int(11)] [daily 1, few times a week 2, few times a] few times a month [] never
11.16	How are you coping with stress? [] very well [] moderate [] with difficulty [] no [self_care_id=17] [int(11)] [very well 1, moderate 2, with difficulty 3,	saved as [0 1 2 3 4] but, there is no category for '0'

Page 3 of 23

Lifestyle - Data is saved in "patient_life_style.csv" and is wide format 10.

10.05	Diet (weekday/	Meal 1	Meal 2	Meal 3	Meal 4	Meal 5	Meal 6	
	routine day) Meal Time (approximate)	[meal1_ampm] [varchar(6)] [AM or PM]	[meal2_ampm] [varchar(6)] [AM or PM]	[meal3_ampm] [varchar(6)] [AM or PM]	[meal4_ampm] [varchar(6)] [AM or PM]	[meal5_ampm] [varchar(6)] [AM or PM]	[meal6_ampm] [varchar(6)] [AM or PM]	-
		:amPm	_:amPm	_:amPm	_:amPm	_:amPm	_:amPm	Commented [CR7]: Should specify [AM or PM]
		[meal1_time] [varchar(5)]	[meal2_time] [varchar(5)]	[meal3_time] [varchar(5)]	[meal4_time] [varchar(5)]	[meal5_time] [varchar(5)]	[meal6_time] [varchar(5)]	
	Туре							Commented [CR8]: Should specify time of the meal
	B=breakfast, L=lunch, D=dinner, S=snack	[meal1_type] [varchar(6)]	[meal2_type] [varchar(6)]	[meal3_type] [varchar(6)]	[meal4_type] [varchar(6)]	[meal5_type] [varchar(6)]	[meal6_type] [varchar(6)]	Commented [CR9]: Should specify type of meal i.e., B=breakfast, L=lunch, D=dinner, S=snack

10.04	Physical Activity (in leisure time) in average			
	week	Days per week	Total time per day	
			Hour(s)	Minutes
	Vigorous	[<mark>pa_vigorous_days_per_week</mark>]	[pa_vigorous_total_hr]	[pa_vigorous_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Moderate	[pa_moderate_days_per_week]	[pa_moderate_total_hr]	[pa_moderate_total_min]
		[int(11)]	[int(11)]	[int(11)]
	Mild	[pa_walking_days_per_week]	[pa_walking_total_hr]	[pa_walking_total_min]
	(Walking)	[int(11)]	[int(11)]	[int(11)]

12. EQ-5D - Data saved in "eq_5d.csv" and is in wide format

Place a tick in one box in each group below for the statement that best describes your own health state today.

12.01 Mobility

[I have no problems in walking about 1, I have some problems in walking about 2, [mobility_id] [int (11)] I am confined to bed 3]

1
I have no problems in walking about

- 2 I have some problems in walking about
- 3 I am confined to bed

12.02 Self-Care [I have no problems with self-care 1, I have some problems with self-care 2,

[self_care_id] [int(11)] I am unable to wash or dress myself 3]

- 1 I have no problems with self-care
- 2 I have some problems with self-care
- 3 I am unable to wash or dress myself

12.03 Usual Activities (e.g. work, study, housework, family or leisure activities) [usual_activities] [int(11)] [I have no problems with performing my usual activities 1, I have some problems with performing my usual activities 2, I am unable to perform my usual activities 3]

- 1 \square I have no problems with performing my usual activities
- 2 I have some problems with performing my usual activities
- 3 I am unable to perform my usual activities

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 4 of 23

12.04 Pain/Discomfort

[pain_discomfort] [int(11)] [I have no pain or discomfort 1, I have moderate pain or discomfort 2, I have extreme pain or discomfort 3]

- 1 🗆 I have no pain or discomfort
- 2 🗆 I have moderate pain or discomfort
- 3 □ I have extreme pain or discomfort

12.05 Anxiety/Depression

[anxiety_depression] [int(11)] [I am not worried or depressed 1; I am moderately anxious or depressed 2, I am extremely anxious or depressed 3]

- 1 🗆 I am not worried or depressed
- 2 \square I am moderately anxious or depressed
- 3 \square I am extremely anxious or depressed

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

I would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.



13. Diabetes Treatment Satisfaction

The following questions are concerned with the treatment for your diabetes (including insulin, tablets, and/or diet) and your experience over the past few weeks. Please answer each question by marking a number on every scale.
13.01 How satisfied are you with your current treatment?
[current_treatment] [int] [0, 1, 2, 3, 4, 5, 6]

Very sa	atisfied 6[]	5[]	4[]	3[]	2[]	Very 1[]	dissatisfied 0[]
	0[]	J[]	4[]	5[]	2[]	11	υ
13.02		ave you felt th ar_high] [int] [/		sugars have be	en unacceptabili	ty high re	ecently?
Mo	ost of the time 6[]		4[]	3[]	2[]	1[]	None of the time 0[]
13.03			nat your blood : [0, 1, 2, 3, 4, 5, 6]	sugars have be	en unacceptabili	ty low re	cently?
Mo	ost of the time 6[]		4[]	3[]	2[]	1[]	None of the time 0[]
13.04	How conver	nient have bee	en finding your	treatment to be	e recently?		
	[convienent	_treat] [int] [0,					
Very c	convenient 6[]	5[]	4[]	3[]	2[]	1[]	Very inconvenient 0[]
13.05				treatment to be	e recently?		
Vo	[flexible_tre ery flexible	at] <mark>[int]</mark> [0, 1, 2,	3, 4, 5, 6]				Very inflexible
ve	6[]	5[]	4[]	3[]	2[]	1[]	0[]
13.06			understandin [0, 1, 2, 3, 4, 5, 6	g of your diabe	tes?		
Very sa	atisfied						dissatisfied
	6[]	5[]	4[]	3[]	2[]	1[]	0[]
13.07		ed would you b <mark>o_treat] [int]</mark> <i>[0</i>		with your prese	nt form of diabet	es treatm	nent?
Very sa	atisfied		45.1	01.1	01.1		dissatisfied
	6[]	5[]	4[]	3[]	2[]	1[]	0[]
13.08		recommend th <mark>d_form] [int]</mark> [0		ment to someo	ne else?		
de rec	es, I would finitely commend s treatment	51.3	45.3				No, I would definitely NOT recommend this treatment

this treatment					this tre
6[]	5[]	4[]	3[]	2[]	1[]

14. Health Utilities Index

This next questionnaire asks about aspects of your health. When answering these questions please think about your health and your ability to do things everyday in the past 4 weeks. To define the 4 week period, please think about what the date was 4 weeks ago and recall the major events that you have experienced during this period. Focus your answers on your overall abilities, disabilities and how you felt during the past 4 weeks.

You may feel that some questions do not apply to you, but it is important that we ask the same questions of everyone. Also, a few questions are similar, but please answer each question independently.

Please read each question and consider answers carefully. For each question, select one answer that best describes your level of ability or disability during the past 4 weeks. Select the answer by checking the box. All information you provide is confidential. There are no right or wrong answers; what we want is your opinion about your abilities/ feelings.

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 6 of 23

0[]

14.01. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to read ordinary newsprint?

[ordinary_news_print] [int] [1, 2, 3, 4]

- $1\square$ a. Able to see well enough without glasses or contact lenses
- 2□ b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses
- 4 d. Unable to see at all

14.02. Which one of the following best describes your ability, during the past 4 weeks, to see well enough to recognize a friend on the other side of the street?

[recognize_friend] [int] [1, 2, 3, 4]

- 1 a. Able to see well enough without glasses or contact lenses
- 2□ b. Able to see well enough with glasses or contact lenses
- 3 c. Unable to see well enough even with glasses or contact lenses
- 4 d. Unable to see at all

14.03. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a group conversation with at least three other people?

[group_conversation] [int] [1, 2, 3, 4, 5]

- $1\square\,$ a. Able to hear what was said without a hearing aid
- 2D b. Able to hear what was said with a hearing aid
- $3\square$ c. Unable to hear what was said even with a hearing aid.
- $4\square\,$ d. Unable to hear what was said, but did not wear a hearing aid
- 5D e. Unable to hear at all

14.04. Which one of the following best describes your ability, during the past 4 weeks, to hear what was said in a conversation with one other person in a quiet room?

[other_person_conversation] [int] [1, 2, 3, 4, 5]

 $1 \square \,$ a. Able to hear what was said without a hearing aid

$2\square\,$ b. Able to hear what was said with a hearing aid

- $3\square$ c. Unable to hear what was said even with a hearing aid
- $4 \Box\,$ d. Unable to hear what was said, but did not wear a hearing aid
- $5\square$ e. Unable to hear at all

14.05. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking your own language with people who do not know you?

[un_own_langauge] [int] [1, 2, 3, 4]

- $1\square\,$ a. Able to be understood completely
- 2 b. Able to be understood partially
- 3□ c. Unable to be understood
- 4 d. Unable to speak at all
- 14.06. Which one of the following best describes your ability, during the past 4 weeks, to be understood when speaking with people who know you well?

[un_other_langauge] [int] [1, 2, 3, 4]

- 1 a. Able to be understood completely.
- 2□ b. Able to be understood partially.
- 3□ c. Unable to be understood.
- 4□ d. Unable to speak at all.
- 14.07. Which one of the following best describes how you have been feeling during the past 4 weeks? [feeling] [int] [1, 2, 3, 4, 5]
- 1□ a. Happy and interested in life
- 2□ b. somewhat happy
- 3□ c. somewhat unhappy
- 4□ d. Very unhappy
- 5□ e. So unhappy that life was not worthwhile
- 14.08. Which one of the following best describes the pain and discomfort you have experienced during

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 7 of 23

the past 4 weeks?

[discomfort_exp] [int] [1, 2, 3, 4, 5]

 $1\square$ a. Free of pain and discomfort

 $2\Box$ b. Mild to moderate pain or discomfort that prevented no activities.

3 c. Moderate pain or discomfort that prevented a few activities

4 d. Moderate to severe pain or discomfort that prevented some activities

5 e. severe pain or discomfort that prevented most activities

14.09. Which one of the following best describes your ability, during the past 4 weeks, to walk? (Note: Walking equipment refers to mechanical supports such as braces, a cane, crutches, or a walker.)

[to_walk] [int] [1, 2, 3, 4, 5, 6]

1 a. Able to walk around the neighborhood without difficulty, and without walking equipment

2 b. Able to walk around the neighborhood with difficulty; but did not require walking equipment

or the help of another person

 $3\square$ c. Able to walk around the neighborhood with walking equipment, but without the help of another person $4\square$ d. Able to walk only short distances with walking equipment, and required a wheelchair to get around the neighborhood

 $5\square$ e. Unable to walk alone, even with walking equipment. Able to walk short distances with the help of another person, and required a wheelchair to get around the neighborhood

6□ f. Unable to walk at all

14.10. Which one of the following best describes your ability, during the past 4 weeks, to use your hands and fingers? (Note: Special tools refer to hooks for buttoning clothes, gripping devices for opening jar or lifting small items, and other devices to compensate for limitations of hand or fingers.) [hands_finger] [int] [1, 2, 3, 4, 5, 6]

1□ a. Full use of hands and ten fingers

2 b. Limitations in the use of hand or fingers, but did not require special tools or the help of another person

 $3\square$ c. Limitations in the use of hands or fingers, independent with use of special tools (did not require the help of another person)

4 d. Limitations in the use of hands or fingers, required the help of another person for some tasks (not independent even with use of special tools)

5 - E. Limitations in the use of hands or fingers, required the help of another person for most tasks (not independent even with use of special tools)

6 f. Limitations in the use of hands or fingers, required the help of another person for all tasks (not independent even with use of special tools)

14.11. Which one of the following best describes your ability, during the past 4 weeks, to remember things?

[remember_things] [int] [1, 2, 3, 4]

 $1\square$ a. Able to remember most things

2□ b. Somewhat forgetful

3□ c. Very forgetful

4 d. Unable to remember anything at all

14.12. Which one of the following best describes your ability, during the past 4 weeks, to think and solve day to day problems?

[think_solve] [int] [1, 2, 3, 4, 5]

1□ a. Able to think clearly and solve day to day problems

2D b. Had a little difficulty when trying to think and solve day to day problems

3 c. Had some difficulty when trying to think and solve day to day problems

4 d. Had great difficulty when trying to think and solve day to day problems

5 e. Unable to think or solve day to day problems

14.13. Which one of the following best describes your ability, during the past 4 weeks, to perform basic activities?

[basic_activity] [int] [1, 2, 3, 4]

1□ a. Eat, bathe, dress and use the toilet normally

 $2 \Box$ b. Eat, bathe, dress and use the toilet independently with difficulty

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 8 of 23

3D c. Required mechanical equipment to eat, bathe, dress or use the toilet independently

4 d. Required the help or another person to eat, bathe, dress or use the toilet

14.14. Which one of the following best describes how you have been feeling during the past 4 weeks? [feeling_health_utility] [int] [1, 2, 3, 4]

- 1 a. Generally happy and free from worry
- 2 b. occasionally fretful, angry, irritable, anxious or depressed
- 3 c. often fretful, angry, irritable, anxious or depressed
- 4 d. extremely fretful, angry, irritable, anxious or depressed; to the point of needing professional help

14.15. Which one of the following best describes the pain or discomfort you have experienced during the past 4 weeks?

[discomfort_health_utility] [1, 2, 3, 4, 5]

1 a. Free of pain and discomfort

2 b. Occasional pain or discomfort. Discomfort relieved by non-prescription drugs or self-control activity without disruption of normal activities

3 c. Frequent pain or discomfort. Discomfort relieved by oral medicines with occasional disruption of normal activities

4 d. Frequent pain or discomfort; frequent disruption of normal activities. Discomfort required prescription narcotics for relief

5 e. Severe pain or discomfort. Pain not relieved by drugs and constantly disrupted normal activities

15&16. Frequency & Costs of Care

Please respond to the following questions regarding outpatient care you received in the previous 12 months. Outpatient care is all instances of clinic visits that did not necessitate hospitalization. (Exclude current visit)

		Indicate number	Month of last visit/test/exar (MMM/yyyy)	n
15.01	Clinic Visits [fpc_clinic_visit_indicate_no] [int(11)]		/	[]unknown
	[fpc_clinic_visit_month_of_visit] [varchar(15)] [fpc_clinic_visit_unknown] [int(11)] [-1]			
15.02	HbA1c testing [fpc_hba_testing_indicate_no] [int(11)] [fpc_hba_testing_month_of_visit] [varchar(15)] [fpc_hba_testing_unknown] [int(11)] [-1]		/	[]unknown
15.03	Cholesterol Testing [fpc_cholestrol_testing_indicate_no] [int(11)] [fpc_cholestrol_testing_month_of_visit] [varchar(15)] [fpc_cholestrol_testing_unknown] [int(11)] [-1]		/	[]unknown
15.04	Foot Exam at clinic [fpc_foot_exam_indicate_no] [int(11)] [fpc_foot_exam_month_of_visit] [varchar(15)] [fpc_foot_exam_unknown] [int(11)] [-1]		/	[]unknown
15.05	Eye Exam [fpc_eye_exam_indicate_no] [int(11)] [fpc_eye_exam_month_of_visit] [varchar(15)] [fpc_eye_exam_unknown] [int(11)] [-1]		/	[]unknown
15.06	Microalbuminuria check [fpc_microal_check_indicate_no] [int(11)] [fpc_microal_check_month_of_visit] [varchar(15)] [fpc_microal_check_unknown] [int(11)] [-1]		/	[]unknown

 $\label{eq:commented_commented_commented_commented_commented} \ensuremath{\mathsf{[r10]}}\xspace: \ensuremath{\mathsf{cm}}\xspace \ensuremath{\sm}\xspace \ensu$ to generated by the system and therefore the date is in DD-MMM-YY format:

[fpc_clinic_visit_month_of_visit] [fpc_hba_testing_month_of_visit]

ipc_nola_lesuing_month_oi_visit] [fpc_cholestrol_testing_month_of_visit] [fpc_eve_exam_unknown] [fpc_eve_exam_month_of_visit] [fpc_ecg_month_of_visit]

[fpc_dental_exam_month_of_visit] [fpc_dietician_visit_month_of_visit]

Commented [CR11]: For Q.Nos. 15.01 – 15.09, specify Indicate number, Month of last visit & unknown If response is [unknown] data is saved as '-1'

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 9 of 23

15.07	ECG	/	[]unknown
	[fpc_ecg_indicate_no] [int(11)]		
	[fpc_ecg_month_of_visit] [varchar(15)]		
	[fpc_ecg_exam_unknown] [int(11)] [-1]		
15.08	Dental Exam	/	[]unknown
	[fpc_dental_exam_indicate_no] [int(11)]		
	[fpc_dental_exam_month_of_visit] [varchar(15)]		
	[fpc_dental_exam_unknown] [int(11)] [-1]		
15.09	Dietician/Diabetes Education	/	[]unknown
	[fpc_dietician_visit_indicate_no] [int(11)]		
	[fpc_dietician_visit_month_of_visit] [varchar(15)]		
	[fpc_dietician_visit_unknown] [int(11)] [-1]		

16.01 What are your sources of finance (give percentages, indicate '0' if not used) FOR:

Outpatient visits?	Inpatient care?
% Out-of-pocket	% Out-of-pocket
[out_of_pocket_opd] [double]	[out_of_pocket_ipd] [double]
% Employer Insurance	% Employer Insurance
[employer_insurance_opd] [double]	[employer_insurance_ipd] [double]
% Private Insurance	% Private Insurance
[private_insurance_opd] [double]	[private_insurance_ipd] [double]
% Government insurance, non-job based	% Government insurance, non-job based
[govt_insurance_opd] [double]	[govt_insurance_ipd] [double]
% Other, please specify:	% Other, please specify:
[other_opd] [double]	[other_ipd] [double]
[other_details_opd] [varchar(200)]	[other_details_ipd] [varchar(200)]
= 100 % total	=100 % total

OUTPATIENT CARE

Please respond to the following questions regarding outpatient care you received for diabetes in the previous **1** year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization. **EXCLUDE current visit**.

Please respond to the following questions regarding outpatient care you received for diabetes in the previous 1
year. Outpatient care is all instances of clinic visits that did not necessitate hospitalization.
EXCLUDE current visit.

16.02	How many outpatient visits did you make in the past 1 year (exclude current visit)?	times
	[out_patient_visit] [int(11)]	
16.03	How many days, including half days, did you miss from work	

for outpatient visits in the past 1 year?	days	[] N/A
[days_miss_work] [int(11)]		

[days_miss_work] [int(11)] [days_miss_work_na] [int(11)] [1]

16.04 List all persons who accompanied you to outpatient visits in the past 1 year:

Person Relation (e.g. father) [person_relation]	Occupation (number*)	Monthly salary [monthly_salary]	Number visits accompanied [number_of_visit]	Commented [r12]: Not in main file
	[occupation]			

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 10 of 23

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

Please list the costs incurred in the past year in relation to outpatient visits:

	Item	Number	Average cost	
		of times	One-time (Rupees)	
16.05	Consultation Fee [con_fee_frq] [int(11)] [avg_con_fee] [double]			Commented [CR13]: For Q.no 16.05 to 16.12
16.06	Lab Tests (HbA1c, blood glucose, urine check) [lab_test_frq] [int(11)] [avg_lab_test] [double]			[frq] indicates "Number of times" & [avg] indicates "Average cost"
16.05	Eye Exam [eye_eam_frq] [int(11)] [avg_eye_exam] [double]			
16.06	ECG [ecg_frq] [int(11)] [avg_ecg_fee] [double]			
16.07	Medicines (tablets, insulin) [med_frq] [int(11)] [avg_med_fee] [double]			
16.08	Supplies (including glucose strips, gauze, sterile solution, etc.) [supply_frq] [int(11)] [avg_supply_fee] [double]			
16.09	Transportation [transport_frq] [int(11)] [avg_transport] [double]			
16.10	Food (personal) [food_personal_frq] [int(11)] [avg_food_personal] [double]			
16.11	Additional cost for escort(s) (e.g. food) [escorts_freq] [int(11)] [avg_escorts] [double]			
16.12	Other out-of-pocket expenses [outpocket_frq] [int(11)] [avg_outpocket_exp] [double]			

INPATIENT CARE

Please respond to the following questions regarding inpatient care you received FOR DIABETES-RELATED COMPLICATIONS* in the previous 1 year. Inpatient care is all instances of medical care that required you to stay in hospital or emergency room.

*chest pain, heart attack, stroke, infection, foot/leg problems, eye problems, kidney problems, blood sugar problem (too high/too low), etc. IF unsure that event is a diabetes-related complication, INCLUDE in listing.

16.13 How many Hospitalizations or Emergency Room visits for diabetes-related complications in the past 1 year?

[hospital_emergency] [int (11)]

16.14 For each of these Hospitalization or Emergency Room Visit, provide details below – (Make sure that visits listed below equals total number listed in 16.13) When providing time, include half-days.

Page 11 of 23

	TYPE	Days	Hospital Co	t Trans	portation	Food	Additional	Person(s)	accompanied (E	Escort) – list a		1	
								1 013011(3)		_30010 11300	411		
	1= Hospitalization, NO		including		including		Escort(s)	Relation	Occupation	Monthly	Days		
	surgery	[durati	medicine/		lance fees		Cost	[person_	(number*)	Salary	accompanied		
	U V	on]	supplies	(total	stay)	<mark>ost]</mark>	[escorts_co	accomp	[occupation]		[days_person		
	3= Emergency Room		(total sta	/) [<mark>[trans</mark>	sport]		st]	ained]	loccabation	_salary]	_accompaine		
	[reason]		[hospital_cost								d]		 Commented [r14]: Not in main sheet
1													
2													
3													
												-	
4													
5													
6												1	

* 1= Employed, 2=Homemaker, 3= Student, 4=Retired, 5= Unemployed/Other

18. Signature of Care Coordinator/Research Officer

Signature:

18.01Name:

Instructions for Continuation (after completion of Form E Part 1)

[] Attach Reports of ECG and Form G-Eye Exam.

[] Control Group: Take participant to STUDY PHYSICIAN to complete PART 2 of Form E. After completion, enter Form E Parts 1 & 2 into eCRF. Include all source documents in patient's trial folder.

[] Intervention Group:

- (1) Enter Form E Sections 1-4 into EHR-DSS (including update of contact information)
- (2) Review patient medications. Update medication changes in writing on Form Z.
- (3) Provide paper Form Z (with medication update) and rest of Form E Part 2 to STUDY PHYSICIAN during consultation with participant.
- (4) Attach completed Form Z to this Form E. Update patient with information.
- (5) After patient leaves, enter Form Z and rest of Form E in eCRF.
- (6) Include all source documents in patient's trial folder.

PART 2: complete by STUDY PHYSICIAN

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 13 of 23

2. ECG and Eye Exam

<u>May use results within past 1 month</u> for ECG and Form G-Eye Exam (attach to end of this form). Otherwise, attempt to complete TODAY, or ensure that <u>testing is done within 2 weeks of today's date</u>. Update in paper and eCRF as soon as available. Retain copies of ECG and eye exam results as source documents.

ECG:

2.01	ECG Date:/ / [s_e	cg_date]	[date]							
	¹ not available form within past month. Scheduled today. update below once results available.									
2.02	Q-waves diagnostic of previous MI [s_ecg_q_waves] [int(11)] [yes 1, No 2]	1[]Y	 → [] hew or worsened [] unchanged or improved 	2[] N						
2.03	Left ventricular hypertrophy [s_ecg_left_ventricular] [int(11)] [yes 1, No 2]	1[]Y	 → [] new or worsened [] unchanged or improved 	2[] N						
2.04	Atrial Fibrillation [s_ecg_atrial] [int(11)] [yes 1, No 2]	1[]Y	 → [] new or worsened [] unchanged or improved 	2[] N						
2.05	Other arrhythmia [s_ecg_other_arrhythmia] [int(11)] [yes 1, No 2]	1[]Y	 → [] new or worsened [] unchanged or improve 	2[] N						

Commented [CR15]: This option is added in CRF

Commented [CR16]: Options (new or worsened & unchanged or improved) are not present at both front-end and back-end for Q.Nos 2.02 to 2.05

EYE EXAM:

May use results from past 1 month.

[] Attach Form G-Eve Exam to end of this Form E – to be completed by qualified ophthalmologist only. If not completed prior to this visit, schedule ophthalmologist appointment and ensure completion within 2 weeks. Enter results in eCRF (EYE EXAM) as soon as available.

12. Complications Update

In the past year, since the last baseline/annual visit, has the patient had any of the following:

	no/unsure	Yes, <u>number</u>	
New/Worsening Blindness in either eye thought to be due to diabetes [h_eyes_blindbess] [no/unsure 0, R 1, L 2, Both 3]	[]	[]R []L	Form X
New/Worsening Glaucoma [h_eyes_glaucoma] [no/unsure 0, R 1, L 2, Both 3]	[]	[]R []L	
New/Worsening Cataract [h_eyes_cataract] [no/unsure 0, R 1, L 2, Both 3]	[]	[]R []L	
Cataract Surgery [h_eyes_cataract_surgery] [no/unsure 0, R 1, L 2, Both 3]	[]	[]R []L	Form X
Laser photocoagulation therapy [h_eyes_laser_therapy] [no/unsure -1, Yes 1]	[]	[eye_laser_therepy_[ft] [<i>Right 1, Left 2</i>] [] R, [eye_laser_therepy_rgt_no] [] L, [eye_laser_therepy_[ft_no]	Form X
Other eye therapy [h_eyes_other_therapy] [1 Yes,-1 No]	[]	[], specify: [h_eyes_other_therapy_spcify]	Form X

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 14 of 23

In the p	ast year, since the last baseline/annual visit, has the patient I	nad any c	of the follow	ving:	
		no/ unsure	Yes, number		
1.11	ACS: Myocardial Infarction or Unstable Angina	und und	<u>Indina e.</u>	Form X	
	[h_cardiovascular_acs] [int(11)] [no/unsure -1, Yes 1]	[]	[]		
	[if Yes 1] \rightarrow [acs_num] [int(11)]				Commented [CR17]: If the response for "h_cardiovascular_acs"
1.12	Angioplasty (PCI) /Open-heart surgery (CABG)	+		Form X	is [Yes 1] specify Number
	[h_cardiovascular_pci_cabg] [int(11)] [no/unsure -1, Yes 1]	[]	[]		
	[if Yes 1] → [pci_num] [int(11)]	1 1	L J		Commented [CR18]: If the response for
1.13	New/Worsened Stable Angina	+	+	Form X	"h_cardiovascular_pci_cabg" is [Yes 1] specify Number
1.10	[stable_angina] [int(11)] [no/unsure -1, Yes 1]	[]	[]		
1.14	Stroke (Ischemic or Hemorrhagic) or TIA	+		Form X	
1.14	[h_cardiovascular_stroke_tia] [int(11)] [no/unsure -1, Yes 1]	r 1			
	$[n_cardiovascular_stroke_traj [nn(11)] [no/unsure -1, Yes 1]$ [if Yes [1] \rightarrow [stroke_num] [int(11)]	[]	[]		
1 15	New/Worsened Arrhythmia (requiring med intervention)	+	+	Form X	Commented [CR19]: If the response for "h_cardiovascular_stroke_tia" is [Yes 1] specify Number
1.15		[]	[]	Form X	
1.10	[h_cardiovascular_arrtythmia] [int(11)] [no/unsure -1, Yes 1]	+			
1.16	New/Worsened Heart Failure	[]	[]	[] if hosp/ER – Form X	
	[h_cardiovascular_heart_attack] [int(11)] [no/unsure -1, Yes 1]	+			
1.28	New/Worsened Neuropathy – hands/feet	[]	[]		
	[h_other_neuropathy_hands_feet] [int(11)] [no/unsure -1, Yes 1]				
1.29	New/Worsened Neuropathy – sexual:erectile dysfunction	[]	[]		
	[h_other_neuropathy_sexual] [int(11)] [no/unsure -1, Yes 1]	1 1			
	New Amputation			Form X	
	[foot_ampu_yesno] [int(11)] [no/unsure -1, Yes 1]	[]	[]		
	[if Yes 1] → [foot_ampu_num] [int(11)]	<u> </u>			Commented [CR20]: If the response for "foot_ampu_yesno" is [Yes 1] specify Number
1.18	Peripheral revascularization (angioplasty/ surgery)			Form X	[Yes 1] specify Number
	[h_peripheral_surgery] [int(11)] [no/unsure -1, Yes 1]	[]	[]		
	[if Yes 1] → [h_peripheral_surgery_year] [varchar(11)]	<u> </u>			Commented [CR21]: If the response for "h_peripheral_surgery"
1.19	Chronic leg/foot ulcer (6 weeks or more) - include current	Γ	Γ	[] if hosp/ER	is [Yes 1] specify Number
	[h_peripheral_foot_ulcer] [int(11)] [no/unsure -1, Yes 1]	[]	[]	– Form X	
	[if Yes 1] → [h_peripheral_foot_ulcer_year] [varchar(11)]	<u> </u>	<u> </u>		Commented [CR22]: If the response for
1.43	Other Major Infection (hospitalization)	[]	[]	Form X	"h_peripheral_foot_ulcer" is [Yes 1] specify Number
	[oth_maj_infec_yesno] [int(11)] [no/unsure -1, Yes 1]				
	[if Yes 1] → [oth_maj_infec_num] [int(11)]				Commented [CR23]: If the response for "oth_maj_infec_yesno"
1.44	Minor Infection (NO hospitalization)		[]		is [Yes 1] specify Number
	[maj_inf_yesno] [int(11)] [no/unsure -1, Yes 1]	[]			
	[if Yes 1] → [maj_inf_num] [int(11)]				Commented [CR24]: If the response for "maj_inf_yesno" is
1.33	New/Worsened Asthma	F ,	Γ.,	[] if hosp/ER	[Yes 1] specify Number
	[h_other_asthma] [int(11)] [no/unsure -1, Yes 1]	[]	[]	– Form X	
1.34	New/Worsened COPD (Chronic Bronchitis, Emphysema)	[]	[]	[] if hosp/ER	
	[h_other_copd] [int(11)] [no/unsure -1, Yes 1]			– Form X	
1.35	New/Worsened Liver disease	[]	[]	[] if hosp/ER – Form X	
1.00	[h_other_liver_disease] [int(11)] [no/unsure -1, Yes 1]				
1.36	New/Worsened Gallbladder disorder (stones, disease) [h_other_gallbladder_disorder] [int(11)] [no/unsure -1, Yes 1]	[]	[]	[] if hosp/ER – Form X	
1.37	New/Worsened Hip Fracture/Replacement	+	+	Form X	
1.07	[h other hip facture] [int(11)] [no/unsure -1, Yes 1]	[]	[]		
	Translation Trial: Form E – Follow-up 12 monthly All v14-30EC2010		Page 15 of 23		

Page 15 of 23

1.38	New/Worsened Depression [h_other_depression] [int(11)] [no/unsure -1, Yes 1]	[]	[]	[] if hosp/ER – Form X	
1.39	Severe HYPOglycemia (hospitalization/ER) [sever_hypoglycemia] [int(11)] [no/unsure -1, Yes 1] [if Yes [1] → [sever_hypoglycemia_num] [int(11)]	[]	[]	Form X	Commented [CR25]: If the response for "sever_hypoglycemia"
	Mild HYPOglycemia [mild_hypoglycemia] [int(11)] [no/unsure -1, Yes 1] [if Yes [1] → [mild_hypoglycemia_num] [int(11)]	[]	[]		is [Yes 1] specify Number Commented [CR26]: Need to check, This variable
1.41	Other major health condition(s), hospitalizations, emergency room visits not listed above, specify: [oth_maj_health_cond] [int(11)] [no/unsure -1, Yes 1]	[]	[]	Form X	"mild_hypoglycemia" is not seen in front-end But present in back-end If the response for "mild_hypoglycemia" is [Yes 1] specify Number Commented [CR27]: If the response "oth_maj_health_cond" is [If Yes 1] no. of times not found
1.42	Total Number of Hospitalizations/emergency room visits from pa				

Complete a Form X for all SAE events listed above. For each hospitalization/emergency room visit, document in source notes, when, where and why it was made. If available, include discharge summary as source document.

1.43	Out of ordinary severe muscle aches/pains [outof_ordinary_musclespain] [int(11)] [Yes 1, No 2]	[]N	[] Y, Obtain CPK
1.44	Medication side effects (i.e. cough from Ace-I, allergic reaction) [medic_side_effect] [int(11)] [Yes 1, No 2]	[]N	[]Y

3. Foot Exam

	Right Foot	Left Foot	
3.01 Amputation	[] N/A	[] N/A	
[fe_amputation_right_foot]	[] toe	[] toe	
[int(11)]	[] ray (metatarsal)	[] ray (metatarsal)	
[fe_amputation_left_foot]	[] forefoot	[] forefoot	
[int(11)]	[] foot	[] foot	
[N/A 1, toe 2, ray (metatarsal) 3, forefoot 4, foot 5,	[] below the knee	[] below the knee	
below knee 6, above knee 7]	[] above the knee	[] above the knee	
3.02 Appearance	1[] normal	1[] normal	
[fe_appearance_right_foot_normal]	2[] abnormal, check all	2[] abnormal, check	Commented [CR28]: If the response is [abno
[int(11)] [normal 1, abnormal 2]	that apply:	all that apply:	below mentioned options 1 to 7 (check all that a & left foot
[fe_appearance_left_foot_normal]	1[] deformities	1[] deformities	
[int(11)] [normal 1, abnormal 2]	2[] dystrophic nails; dry skin/fissure	2[] dystrophic nails; dry skin/fissure	[fe_appearance_left_foot_deformities] [int(11)]
[fe_appearance_right_foot_deformities] [int(11)] [1		3[] callus	[fe_appearance_left_foot_dystrophic] [int(11)]
[fe_appearance_right_foot_dystrophic] [int(11)] [2]	4[] ulceration	4[] ulceration	[fe_appearance_left_foot_callus] [int(11)] [3] [fe_appearance_left_foot_unceration] [int(11)]
[fe_appearance_right_foot_callus] [int(11)] [3]	CL 1 is far stirm	5[] infection	[fe_appearance_left_foot_infection] [int(11)] /5
[fe_appearance_right_foot_unceration] [int(11)] [4]	6[] discoloration	6[] discoloration	[fe_appearance_left_foot_dys] [int(11)] [6]
[fe_appearance_right_foot_infection] [int(11)] [5] [fe_appearance_right_foot_dys] [int(11)] [6]	7[] other:	7[] other:	[fe_appearance_left_foot_other] [int(11)] [7]
[fe_appearance_right_foot_other] [int(11)] [7]			[fe_appearance_left_foot_other_d]
[fe_appearance_right_foot_otherd]			[varchar(200)] [other specify]
[varchar(200)] [other specify]			
3.03 Posterior tibial pulse	1[] 2[]N	1[]Y 2[]N	
[fe_posterior_right_foot] [int(11)] [Yes 1, No	V		
[fe_posterior_left_foot] [int(11)] [Yes 1, No 2	_		

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_v1.4-3DEC2010

Page 16 of 23

3.04	Doraslis pedis pulse [fe_doraslis_right_foot] [int(11)] [Yes 1, No. [fe_doraslis_left_foot] [int(11)] [Yes 1, No.		1[] Y	2[] N	1[] Y	2[] N	
3.05	Pre-tibial EDEMA today [fe_pre_tibial_edema_right_foot] [int(11)] [fe_pre_tibial_edema_left_foot] [int(11)] [None 0, up to ankle 1,between ankle & mid-calf 2, between mid-calf & knee 3]		calf		calf	ankle een ankle & mid een mid-calf &	
3.06	Ankle Reflex [fe_ankle_relax_right_foot] [int(11)] [Yes 1, No 2] [fe_ankle_relax_left_foot] [int(11)] [Yes 1, No 2]		1[]Y	2[] N	1[] Y	2[]N	
3.07	Knee Reflex [fe_knee_reflax_right_foot] [int(11)] [Yes 1, No 2] [fe_knee_reflax_left_foot] [int(11)] [Yes 1, No 2]		1[]Y	2[] N	1[] Y	2[]N	
3.08	Vibration, tuning fork (perception at grea [fe_vibration_right_foot] [int(11)] [fe_vibration_left_foot] [int(11)] [present (≥10 sec) 1, reduced (<10 sec) 2, absent	[] reduced (<10 sec) [] absent		ced (<10 sec)	[] present (≥10 sec) [] reduced (<10 sec) [] absent		
3.09	10g Monofilament (number applications detected) [fe_monofilament_right_foot] [int(11)] [fe_monofilament_left_foot] [int(11)] [present (≥8) 1, reduced (1-7) 2, absent 3]		[] prese [] reduc [] abse	ced (1-7)	[] presen [] reduce [] absent	d (1-7)	
	Assessment						
3.10	Deformities [fe_participant_has] [varchar(20)] [Yes 1, No -1]		[] u amputati	ew or worsened inchanged or impro on_newunch <mark>] [int(</mark> unchanged or improve	11)]	2[] N	Commented [CR29]: Q.no.3.10-3.14 has multiple responses data stored in this column as string so we are splitting & re nam the categories as
3.11	Foot ulceration/infection [Yes 2, No -2] [assm_foot_ulcer_newunch] [int(11)] [new or worsened 1, unchanged or improved 0]		→[]n	ew or worsened inchanged or impro		2[] N	 [1,-1, 2,-2, 3,-3, 4,-4] Commented [CR30]: Doubt about the naming convention o this variable but based on values, taken as [assm_amputation_newunch]
3.13	PVD [Yes 3, No -3] [assm_pvd_newunch] [int(11)] [new or worsened 1, unchanged or improved 0]	1[] Y		ew or worsened nchanged or impro	oved	2[]N	
3.14	Neuropathy [Yes 4, No -4] [assm_neuropathy_newunch] [int(11)] [new or worsened 1, unchanged or improved 0]	1[] Y	 ✓ → [] new or worsened [] unchanged or impro 		2[]N		
14.	Heart Failure Exam						
	Have you experienced any of the foll	owing s	ince you	r last exam?			
4.01	swelling of your feet, ankles or legs [hf_swelling_feet] [int(11)] [Yes 1, No 2, N/A 3] [if Yes 1] →	1[]Ye 2[]No	(es → 1[] new or worsened				Commented [CR31]: If the response is [yes 1] for Q.no.4.01 4.03 – specify '1' or '0' [new or worsened 1, unchanged or improved 0]

Page 17 of 23

4.02	shortness of breath while lying, sitting, or with minimal exertion [hf_shortness_of_breath] [int(11)] [Yes 1, No 2, N/A 3] [if Yes 1] →	1[]Yes → 2[]No	 1[] new or worsened 2[] unchanged or improved [hf_is_shortness_of_breath_new] [new or worsened 1, unchanged or improved 0]
4.03	need to pass urine two or more times per night [hf_pass_urine] [int(11)] [Yes 1, No 2, N/A 3] [if Yes 1] →	1[]Yes → 2[]No	 1[] new or worsened 2[] unchanged or improved [hf_is_pass_urine_new] [new or worsened 1, unchanged or improved 0]

If any 4	f any 4.01-4.03 is YES, complete below.					
Chest	Auscultation					
4.04	Lungs [hf_chest_ausculation_lungs] [int(11)] [no rales 1, basilar rales only 2, more than basilar 3]	1[] no rales 2[] basilar rales only 3[] more than basilar				
4.05	Heart [hf_chest_ausculation_heart] [int(11)] [normal 1, abnormal 3rd heart sound present 2]	1[] normal 2[] abnormal, 3 rd heart sound present				

4.06	Heart Failure evident	1[] Y \rightarrow [] new or worsened	2[]N	
	[hf_chest_ausculation_heart_failure] [int(11)]	[] unchanged or improved		
	[Yes 1, No 2]			
				Commented [CR32]

5. Neurological Exam

	Have you experienced any of the following since your last exam?				
	Muscle weakness	1[]Y → [] new or worsened	2[]N		
5.01	[ne_muscles_weakness] [int(11)]	[] unchanged or improved			
	[Yes 1, No 2, N/A 3] [if Yes 1] →	[ne_is_muscles_weakness_new] [int(11)]			
	Difficulty in speech [ne_difficulty_in_speech] [int(11)]	Inew or worsened 1 unchanged or improved 01 1[]Y → [] new or worsened [] unchanged or improved	2[]N		
5.02	[Yes 1, No 2, N/A 3] [if Yes 1] →	[ne_difficulty_in_speech_new] [int(11)] [new or worsened 1, unchanged or improved 0]			
5.03	Loss of consciousness [ne_loss_consciousness] [int(11)]	1[]Y → [] new or worsened [] unchanged or improved	2[]N		
0.00	[Yes 1, No 2, N/A 3]	[ne_is_loss_consciousness] [int(11)] [new or worsened 1, unchanged or improved 0]			

ommented [CR32]: Variable not found

Commented [CR33]: If the response is [yes 1] for Q.no.5.01 & 5.02 – specify '1' or '0' [new or worsened 1, unchanged or improved 0]

If any	If any 5.01-5.03 is YES, complete below.				
	Muscles	Right	Left		
5.04	ARMS-Tone [ne_arms_tone_right] [int(11)] [ne_arms_tone_left] [int(11)] [normal 1, flaccid 2, rigid/spastic 3]	[]normal []flaccid []rigid/spastic	[]normal []flaccid []rigid/spastic		
5.05	ARMS-Strength [ne_arms_strengt_right] [int(11)] [ne_arms_strengt_left] [int(11)]	[] normal [] deficit	[] normal [] deficit		
CARRS T	CARRS Translation Trial; Form E - Follow-up 12 monthly All v1.4-3DEC2010 Page 18 of 23				

ige 18

	[normal 1, deficit 2]		
5.06	LEGS-Tone [ne_legs_tone_right] [int(11)] [ne_legs_tone_left] [int(11)] [normal 1, flaccid 2, rigid/spastic 3]	[] normal [] flaccid [] rigid/spastic	[] normal [] flaccid [] rigid/spastic
5.07	LEGS-Strength [ne_legs_strength_right] [int(11)] [ne_legs_strength_left] [int(11)] [normal 1, deficit 2]	[] normal [] deficit	[]normal []deficit
	Reflexes	Right	Left
5.08	Biceps [ne_reflexes_biceps_right] [int(11)] [ne_reflexes_biceps_left] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent
5.09	Triceps [ne_reflexes_triceps_right] [int(11)] [ne_reflexes_triceps_left] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent
5.10	Knee [ne_reflexes_knee_right] [int(11)] [ne_reflexes_knee_right] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent
5.11	Ankle [ne_reflexes_ankle_right] [int(11)] [ne_reflexes_ankle_left] [int(11)] [present 1, absent 2]	[]present []absent	[]present []absent
5.12	[ne_old_deficit] [int(11)] [Yes 1, No 2] [ne_ol	→ [] new or worsened [] unchanged or improv Id_deficit_newunch] [int(11)] worsened 1, unchanged or improved	

Page 19 of 23

FORM E – Follow-up 12 mont	hly	Participant ID:
CARRS Translation Trial	Participant Name:	Initials:
Complete by CC, RO, and SP	Date of Visit (dd/M	MM/yyyy): / /

6. MEDICATIONS and MANAGEMENT

6.01	Drug Allergies [other_drug_allergies] [ir			[]no/unknown [] yes, specify any changes since baseline: [if Yes 1] → [drug_allergies] [varchar(20)]						Commented [CR34]: If the response is [Yes 1] specify the
6.02	[Yes 1, No 2, unknown -1] MEDICATIONS – CONT			E 1.NJ/A IN	ITERVENTION	GROUP	changes			
Below, li ^For (1)	ist all medications that the Insulin, (2) OHAs, and (e all constituents separa	participa 3) Blood								
Туре	Brand Name [name] [varchar(200)]	Ger [generic [varchar	^List ALL cons Insulin, OHAs, eric Name _name] (200)]	tituents for BP meds Single Dose [single_dose] [double]	- Frequency [frequency] [double	Total daily dose [total_daily_ dose] [double]				
Insulin										
OHAs										
<u></u>										
вр										
Lipid-										
lowerin										
g										

CARRS Translation Trial; Form E - Follow-up 12 monthly_All_v1.4-3DEC2010

Page 20 of 23

FORM E -	- Follow-up 12 mont		Participant ID:			
	anslation Trial by CC, RO, and SP	Participant Name: Date of	f Visit (dd/MMM/yyyy)			
Blood-	, , ,			/ /		
thinner						
Туре	Brand Name	Generic Name	Single Dose	Frequency	Total daily dose	
Other						

CONTROL GROUP: Review Form E with Principal Investigator/Co-Investigator. Have PI/Co-I make any changes to medications above. Strike out old medications and write in changed/new medications. Make sure final medication list is obvious and legible. Attach prescription with updated medications as source document.

→ COMPLETE BELOW FOR CONTROL AND INTERVENTION PARTICIPANTS.

6.03		Management of diabetes in last 6 months [dibetes_mgt] [varchar(50)]	[Sulphonylurea (glibenclamide, gliclazide, glimipiride) 1 Biguanide (Metformin) 2
	[]	Sulphonylurea (glibenclamide, gliclazide, glimipiride)	Thazolidineodione (Pioglitazone) 3
	[]	Biguanide (Metformin)	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)4
	[]	Thazolidineodione (Pioglitazone)	Glinide (Nateglinide, Repaglinide, Mitiglinide) 5
	[]	Alpha-glucosidase inhibitor (acarbose, miglitol, voglibose)	Lispro, Aspart, Glulisine insulins (rapid-acting) 6
	[]	Glinide (Nateglinide, Repaglinide, Mitiglinide)	Regular Insulins (short-acting) 7
	[]	Lispro, Aspart, Glulisine insulins (rapid-acting)	NPH or Lente Insulins (intermediate-acting) 8 Glargine or Determir Insulins (very long-acting) 9
	[]	Regular Insulins (short-acting)	Other diabetic treatment 10
	[]	NPH or Lente Insulins (intermediate-acting)	Dietician or Educator referral 11
	[]	Glargine or Determir Insulins (very long-acting)	Weight control or exercise program 12
		Field Form F. Follow up 42 monthly: All a construction	Home blood glucose monitoring 13

CARRS Translation Trial; Form E – Follow-up 12 monthly_All_ v1.4-3DEC2010

Page 21 of 23

FORM E	– Follo		int ID:	
CARRS T	ranslatio		Initials:	
Complete	by CC	, RO, and SP Date of Visit (dd/MMM/yyyy):	//	
	[]	Other diabetic treatment		
	[]	Dietician or Educator referral		
	[]	Weight control or exercise program		-
	[]	Home blood glucose monitoring		-
6.04		Other medications		
		[other_dibetes_mgt] [varchar(100)]		
	[]	Thaizide or thiazide-like diuretic		Thaizide or thiazide-like diuretic 1
	[]	Other diuretic		Other diuretic 2
	[]	ACE inhibitor		ACE inhibitor 3
	[]	Angiotensin 2 receptor antagonist (ARB)		Angiotensin 2 receptor antagonist (ARB) 4
	[]	Beta-blocker		Beta-blocker 5 Calcium channel blocker (CCB) 6
	[]	Calcium channel blocker (CCB)		Other antihypertensive agent 7
	[]	Other antihypertensive agent		Statin 8
	[]	Statin		Other cholesterol lowering drug 9
	[]	Other cholesterol lowering drug		Aspirin 10
	[]	Aspirin		Other anti-platelet agent 11
	[]	Other anti-platelet agent		Oral anticoagulant 12 Nitrates (NOT sublingual) 13
	[]	Oral anticoagulant		Hormone replacement therapy 14
	[]	Nitrates (NOT sublingual)		Thyroid Agents 15
	[]	Hormone replacement therapy		Oral/inhaled steroids 16
	[]	Thyroid Agents		Oral asthma drugs (exclude steroids) 17
	[]	Oral/inhaled steroids		Antidepressant 18 Anti-neuropathy medications (gabapentin, pregabalin,
	[]	Oral asthma drugs (exclude steroids)		amatryptiline) 19
	[]	Antidepressant		Erectile Dysfunction drug 20
	-	Anti-neuropathy medications (gabapentin, pregabalin, amatryp	tilina)	Herbal/alternative medicine 21
	[]	Erectile Dysfunction drug		Vitamins/nutritional supplements 22
	[]			Other, not listed above 23
	[]	Herbal/alternative medicine		-
	[]	Vitamins/nutritional supplements		-
	[]	Other, not listed above		

7.	DATA OBTAINED	[fe_data_obtained_option	n_value]	
	[fe_data_obtained_option]	 1[] Y → Assessment type: [] Phone call with patient [4] [] Clinic / In person [5] [] Phone call or contact with relative [6] [] Phone call or contact with other health care provider [7] [] Other, Specify [8] [fe_data_obtained_option_yes_other] 	 2[] N → Reason not obtained: [] Not Done [0] [] Refuses further participation [1] [] Unable to contact participant [2] [] Patient died [3] 	Commented [r35]: Response as Yes (1) or No (2)

Page 22 of 23

FORM E – Follow-up 12 month	ly	Participant ID:	
CARRS Translation Trial	Participant Name:	Initials	:
Complete by CC, RO, and SP	Date of Visit (dd	l/MMM/yyyy): / / / / /	

8.	ignature of Physician

8.01 Name: ______ Signature: _____

8.02 Date Signed: ___ / ___ / ___ / ____

Page 23 of 23