THE LANCET
Diabetes & Endocrinology

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Gong Q, Zhang P, Wang J, et al. Morbidity and mortality after lifestyle intervention for people with impaired glucose tolerance: 30-year results of the Da Qing Diabetes Prevention Outcome Study. *Lancet Diabetes Endocrinol* 2019; published online April 25. http://dx.doi.org/10.1016/S2213-8587(19)30093-2.

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to:

Gong Q, Zhang P, Wang J, et al. Morbidity and mortality after lifestyle intervention for people with impaired glucose tolerance: 30-year results of the Da Qing Diabetes Prevention Outcome Study.

Supplementary Appendix

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	Control	Intervention	HR * (95%CI) Intervention/Control	P-value
Diabetes ‖				
Cases/Person-years	126/1072	337/4765		
Cumulative incidence (%, 95%CI)	95·9 (89·1-98·5)	88·7 (84·6-91·8)		
Cases per 1000 person-years (95%CI)	117·5 (97·9-139·9)	70·7 (63·4-78·7)	0·61 (0·45-0·83)	0·0015
CVD Events †				
Cases/ Person-years	80/2715	195/8776		
Cumulative incidence(%, 95%CI)	66·5 (57·0–74·4)	52·9 (47·5–57·9)		
Cases per 1000 person-years(95%CI)	29·5 (23·4-36·7)	22·2 (19·2-25·6)	0·74 (0·59-0·92)	0·0060
Composite Microvascular Disease ‡				
Cases/ Person-years	33/2974	76/9771		
Cumulative incidence(%, 95%CI)	34·0(24·5-43·8)	25·1 (20·2-30·1)		
Cases per 1000 person-years(95%CI)	11·1 (7·6-15·6)	7·8 (6·1-9·7)	0·65 (0·45-0·95)	0·0245
CVD Deaths §				
Cases/ Person-years	40/3179	89/10240		
Cumulative incidence(%, 95%CI)	35·2 (26.4-44.2)	25·6 (21·1-30·4)		
Cases per 1000 person-years(95%CI)	12·6 (9.0-17.1)	8·7 (7.0-10·7)	0·67(0·48-0·94)	0·0220
All-cause Mortality				
Cases/ Person-years	76/3179	185/10240		
Cumulative incidence(%, 95%CI)	56·3 (47·4-64·2)	45·5 (40·5-50·2)		
Cases per 1000 person-years(95%CI)	23·9 (18·8-29·9)	18·1 (15·6-20·9)	0·74 (0·61-0·89)	0·0015

Cumulative incidence at 30 years calculated by Kaplan-Meir method.

* HR: Hazard Ratio and P value from Cox proportional hazard models, controlled for clinic randomisation.

‖ Diabetes defined from results of the oral glucose tolerance test done every 2 years during the trial (1986–1992), and in 2006 or 2016 at the follow-up examinations, or by self-reported physician-diagnosed diabetes with evidence of elevated glucose levels in the medical record, or receiving hypoglycemic medications.

† CVD events defined as non-fatal or fatal myocardial infarction, or sudden death, hospitalization for heart failure, or non-fatal or fatal stroke.

‡ Composite microvascular disease defined as an aggregate of retinopathy, nephropathy, or neuropathy.

§ CVD deaths defined as death due to myocardial infarction, sudden death, heart failure, or stroke.

Table S1. Cumulative Incidence, Incidence Rate and Hazard Ratio for Primary Outcome Events in the Control and Intervention Groups at the End of the 30-year Follow-up.

Amendment to diagnostic criteria for microvascular complications

Criteria for outcome measures for the 30-year follow-up were predefined in the 2016 study protocol. For the microvascular outcomes of retinopathy, nephropathy, and neuropathy, the predefined criteria included some elements such as e-GFR, urinary albumin/creatinine ratio and abnormal monofilament tests which were measured only in the examined living participants. We failed to anticipate that mortality rates would be so different in the control and intervention groups, and that the proportion of survivors would be appreciably larger in the intervention group. These findings resulted in biased ascertainment of these elements between the control and intervention groups due to competing mortality. This leads to overestimation of these elements in the intervention compared with the control group, and potentially to underestimation of differences in the effects of intervention.

To address and minimize this bias for the present report, we have amended criteria for the microvascular outcomes excluding those elements which were assessed only in the examined, surviving participants, and retaining the criteria that can be reliably ascertained from medical records, which leads to a more accurate assessment of the effects of intervention. Consequently, incidence rates and hazard ratios for retinopathy, nephropathy and neuropathy that we report in the main paper for the 30-year follow-up are not directly comparable to those previously reported for the 20-year follow-up study.

Hazard Ratios for Effects of Intervention using Protocol Defined and Amended Criteria for Microvascular Disease.

	Protocol defined criteria		Amended criteria	
Outcomes	**Hazard ratio (95% CI)**	**P**	**Hazard ratio (95% CI)**	**P**
Composite microvascular disease	0·72 (0·52-0·99)	0·044	0·65 (0·45-0·95)	0·025
Retinopathy	0·60 (0·38-0·95)	0·032	0·60 (0·38-0·95)	0·032
Nephropathy	1·04 (0·74-1·48)	0·81	0·68 (0·36-1·28)	0·24
Neuropathy	0·60 (0·33-1·10)	0·10	0·57 (0·24-1·36)	0·21

	Control	Intervention	HR * (95%CI) Intervention/Control	P-value
Stroke †				
Cases/ Person-years	62/2726	156/8967		
Cumulative incidence(%, 95%CI)	55·1 (45·0–64·1)	43·3 (38·1–48·4)		
Cases per 1000 person-years(95%CI)	22·7 (17·4-29·2)	17·4 (14·8-20·4)	0·75 (0·59-0·96)	0·024
Coronary Heart Disease ‡				
Cases/ Person-years	26/3134	61/9905		
Cumulative incidence(%, 95%CI)	24·5 (16·7-33·2)	18·6 (14·5-23·1)		
Cases per 1000 person-years(95%CI)	8·3 (5·4-12·2)	6·2 (4·7-7·9)	0·73 (0·51-1·04)	0·079
Heart Failure §				
Cases/ Person-years	16/3159	39/10197		
Cumulative incidence(%, 95%CI)	18·1 (10·8-26·9)	13·7 (9·9-18·0)		
Cases per 1000 person-years(95%CI)	5·1 (2·9-8·2)	3·8 (2·7-5·2)	0·71 (0·48-1·04)	0·081
Retinopathy ¶				
Cases/ Person-years	26/2912	56/9683		
Cumulative incidence(%, 95%CI)	28·3 (19·0-38·2)	18·9 (14·6-23·7)		
Cases per 1000 person-years(95%CI)	8·9 (5·8-13·1)	5·8 (4·4-7·5)	0.60 (0.38-0.95)	0·032
Nephropathy ǀ				
Cases/ Person-years	7/3170	16/10213		
Cumulative incidence(%, 95%CI)	8·1 (3·5-15·1)	5·4 (3·2-8·4)		
Cases per 1000 person-years(95%CI)	2·2 (0·9-4·5)	1·6 (0·9-2·6)	0·68 (0·36-1·28)	0·24
Neuropathy **				
Cases/ Person-years	7/3154	14/10207		
Cumulative incidence(%, 95%CI)	7·8 (3·4-14·6)	5·0 (2·8-8·0)		
Cases per 1000 person-years(95%CI)	2·2 (0·9-4·6)	1·4 (0·7-2·3)	0·57(0·24-1·36)	0·21

Cumulative incidence at 30 years calculated by Kaplan-Meir method.
* HR: Hazard Ratio and P value from Cox proportional hazard models, controlled for clinic randomisation.
† Stroke defined as non-fatal or fatal stroke.
‡ Coronary heart disease defined as non-fatal or fatal myocardial infarction or sudden death.
§ Heart failure defined as hospitalization for heart failure.
¶ Retinopathy defined as a history of photocoagulation, blindness from retinal disease, or proliferative retinopathy.
ǀ Nephropathy defined as a history of end-stage renal disease, renal dialysis, renal transplantation, death from chronic kidney disease.
** Neuropathy defined as a history of lower extremity ulceration, gangrene or amputation.

Table S2. Cumulative Incidence, Incidence Rate and Hazard Ratio for Secondary Outcome Events in the Control and Intervention Groups at the End of the 30-year Follow-up.

	Control		Intervention		HR(95%CI) *	P value
		Person-years =3179		Person-years =10240	Intervention/Control	
	N	Rate (95%CI)	N	Rate (95%CI)		
All-cause Death	76	23·9 (18·8-29·9)	185	18·1 (15·6-20·9)	0·74 (0·61-0·89)	0·0015
CVD Deaths †	40	12·6 (9·0-17·1)	89	8·7 (7·0-10·7)	0·67 (0·48-0·94)	0·022
Stroke	18	5·7 (3·4-8·9)	45	4·4 (3·2-5·9)	0·76 (0·44-1·34)	0·35
CHD ‡	16	5·0 (2·9-8·2)	32	3·1 (2·1-4·4)	0·60 (0·31-1·15)	0·12
Heart Failure	6	1·9 (0·7-4·1)	12	1·2 (0·6-2·0)	0·60 (0·26-1·37)	0·23
Non-CVD Deaths	36	11·3 (7·9-15·7)	96	9·4 (7·6-11·4)	0·81 (0·52-1·26)	0·35
Cancer	14	4·4 (2·4-7·4)	43	4·2 (3·0-5·7)	0·95 (0·52-1·72)	0·85
Infection	11	3·5 (1·7-6·2)	19	1·9 (1·1-2·9)	0·52 (0·27-0·99)	0·05
COPD §	2	0·6 (0·1-2·3)	8	0·8 (0·3-1·5)	1·23 (0·36-4·28)	0·74
Renal failure	1	0·3 (0·1-1·8)	8	0·8 (0·3-1·5)	2·39 (0·40-14·28)	0·34
Diabetes ¶	2	0·6 (0·1-2·3)	5	0·5 (0·2-1·1)	0·77 (0·18-3·23)	0·72
Injury	0		5	0·5 (0·2-1·1)	-	-
Cirrhosis	2	0·6 (0·1-2·3)	1	0·1 (0·0-0·5)	0·16 (0·02-1·74)	-
Other ‖	0		3	0·3 (0·0-0·9)	-	-
Unknown **	4	1·3 (0·3-3·2)	4	0·4 (0·11-1·0)	0·28 (0·10-0·78)	-

* HR: Hazard Ratio and P value from Cox proportional hazard models, controlled for clinic randomisation.

† CVD deaths defined as death due to myocardial infarction, sudden death, heart failure, or stroke.

‡ CHD: Death from coronary heart disease (myocardial infarction or sudden death).

§ COPD: Chronic obstructive pulmonary disease.

¶ Diabetes: Death from ketoacidosis, or hyperosmolar coma.

‖ Other: including bleeding of upper digestive tract, or multi-organ failure.

**Unknown: unknown causes.

Table S3. Cause-specific Death Rates (per 1000 person-years) in the Control and Intervention Groups.

Variable	Hazard Ratio	95% CI	P value
CVD Events (275 events)			
Age—years	1·06	1·05-1·08	<0·0001
Sex (male=1)	1·56	1·21-2·01	0·0006
Intervention (yes=1)	0·88	0·67-1·14	0·33
Diabetes onset (yes=1) *	2·02	1·48-2·74	<0·0001
Composite Microvascular Disease (109 events)			
Age—year	1·02	0·99-1·05	0·067
Sex (male=1)	0·93	0·63-1·38	0·98
Intervention (yes=1)	0·73	0·48-1·10	0·13
Diabetes onset (yes=1) *	3·25	1·42-7·45	0·0053
CVD Deaths (129 deaths)			
Age—year	1·10	1·07-1·13	<0·0001
Sex (male=1)	1·93	1·30-2·85	0·001
Intervention (yes=1)	0·82	0·56-1·20	0·31
Diabetes onset (yes=1) *	1·65	1·03-2·62	0·035
All-cause Mortality (261 deaths)			
Age—year	1·09	1·08-1·11	<0·0001
Sex (male=1)	2·0	1·52-2·65	<0·0001
Intervention (yes=1)	0·92	0·70-1·20	0·53
Diabetes onset (yes=1) *	1·72	1·24-2·37	0·001

*Diabetes onset calculated as a time-dependent variable was used to estimate the effect of the delay in onset of diabetes. Its inclusion in an extended Cox model negates the significance of intervention on hazard ratios for the primary outcome events, indicating that delay in diabetes-onset in the intervention group can explain much of the difference in the incidence of outcome events in the control and intervention groups.

Table S4. Multivariable Models showing effect of correcting for Time of Onset of Diabetes on Hazard Ratio for Primary Outcome Events.

	Control	Intervention	HR * (95%CI) Intervention/Control	P value
Men				
Diabetes §				
Cases/Person-years	70/619	171/2562		
Cumulative incidence (%, 95%CI)	93·7 (72·0-99·6)	83·6 (76·9-88·5)		
Cases per 1000 person-years (95%CI)	113·1 (88·2-142·9)	66·7 (57·1-77·5)	0·61 (0·44-0·83)	0·0018
CVD events †				
Cases/ Person-years	51/1442	122/4291		
Cumulative incidence (%, 95%CI)	74·2 (61·5–83·2)	63·3 (55·8–69·9)		
Cases per 1000 person-years (95%CI)	35·4 (26·3-46·5)	28·4 (23·6-33·9)	0·80 (0·60-1·06)	0·12
Stroke‡				
Cases/ Person-years	40/1444	101/4362		
Cumulative incidence (%, 95%CI)	62·9 (48·8–74·1)	53·9 (46·1–61·0)		
Cases per 1000 person-years (95%CI)	27·7 (19·8-37·7)	23·2 (18·9-28·1)	0·83 (0·61-1·11)	0·21
Coronary Heart Disease¶				
Cases/ Person-years	19/1668	39/4962		
Cumulative incidence (%, 95%CI)	33·5 (21·2-46·2)	24·2 (17·7-31·3)		
Cases per 1000 person-years (95%CI)	11·4 (6·9-17·8)	7·9 (5·6-10·7)	0·68 (0·43-1·10)	0·11
Heart Failure ‖				
Cases/ Person-years	10/1699	25/5127		
Cumulative incidence (%, 95%CI)	21·6 (10·9-34·6)	18·7 (12·5-25·9)		
Cases per 1000 person-years (95%CI)	5·9 (2·8-10·8)	4·9 (3·2-7·2)	0·81 (0·41-1·60)	0·55
Composite Microvascular Disease **				
Cases/ Person-years	17/1596	34/4956		
Cumulative incidence (%, 95%CI)	31·4 (19·3-44·3)	23·2 (16·4-30·6)		
Cases per 1000 person-years (95%CI)	10·7 (6·2-17·1)	6·9 (4·8-9·6)	0·61 (0·35-1·06)	0·081
Retinopathy §§				
Cases/ Person-years	13/1537	22/4921		
Cumulative incidence (%, 95%CI)	24·3 (13·5-36·8)	14·9 (9·5-21·5)		
Cases per 1000 person-years (95%CI)	8·5 (4·5-14·5)	4·5 (2·8-6·8)	0·50 (0·25-1·002)	0·051
Nephropathy ††				
Cases/ Person-years	6/1697	8/5147		
Cumulative incidence (%, 95%CI)	13·1 (5·1-24·8)	5·7 (2·6-10·6)		
Cases per 1000 person-years (95%CI)	5·3 (2·4-10·1)	3·3 (1·9-5·3)	0·43 (0·18-1·04)	0·061
Neuropathy ‡‡				
Cases/ Person-years	4/1698	10/5134		
Cumulative incidence (%, 95%CI)	8·8 (2·7-19·4)	7·4 (3·7-12·7)		
Cases per 1000 person-years (95%CI)	2·4 (0·6-6·0)	1·9 (0·9-3·6)	0·79 (0·21-2·95)	0·72
CVD Deaths ¶¶				
Cases/ Person-years	28/1706	63/5157		
Cumulative incidence(%, 95%CI)	46·0 (32·6-58·5)	36·3 (29·0-43·7)		
Cases per 1000 person-years(95%CI)	16·4 (10·9-23·7)	12·2 (9·4-15·6)	0·73 (0·47-1·12)	0·15
All-cause Mortality				
Cases/ Person-years	52/1706	135/5157		
Cumulative incidence(%, 95%CI)	67·5 (55·6-76·8)	60·9 (54·1-67·0)		
Cases per 1000 person-years(95%CI)	30·5 (22·8-40·0)	26·2 (21·9-31·0)	0·85 (0·66-1·09)	0·19
Women				
Diabetes §				
Cases/Person-years	56/453	166/2203		
Cumulative incidence (%, 95%CI)	96·6 (84·7-99·3)	92·9 (87·6-96·0)		
Cases per 1000 person-years (95%CI)	123·6 (93·4-160·5)	75·4 (64·3-87·7)	0·62 (0·42-0·92)	0·017
CVD events†				
Cases/ Person-years	29/1273	73/4485		
Cumulative incidence(%, 95%CI)	56·5 (41·4–69·1)	41·7 (34·2–48·9)		
Cases per 1000 person-years(95%CI)	22·8 (15·3-32·7)	16·3 (12·8-20·5)	0·69 (0·51-0·92)	0·013
Stroke‡				
Cases/ Person-years	22/1282	55/4605		
Cumulative incidence (%, 95%CI)	45·1 (30·3–58·8)	31·5 (24·7–38·5)		
Cases per 1000 person-years (95%CI)	17·2 (10·8-26·0)	11·9 (9·0-15·5)	0·68 (0·48-0·96)	0·028
Coronary Heart Disease ¶				
Cases/ Person-years	7/1466	22/4943		
Cumulative incidence (%, 95%CI)	14·4 (6·2-25·8)	13·4 (8·7-19·1)		
Cases per 1000 person-years (95%CI)	4·8 (1·9-9·8)	4·5 (2·8-6·7)	0·92 (0·39-2·13)	0·84
Heart Failure ‖				
Cases/ Person-years	6/1460	14/5070		
Cumulative incidence (%, 95%CI)	14·4 (5·7-26·9)	9·2 (5·3-14·5)		
Cases per 1000 person-years (95%CI)	4·1 (1·5-8·9)	2·8 (1·5-4·6)	0·60 (0·29-1·25)	0·17
Composite Microvascular Disease**				
Cases/ Person-years	16/1378	42/4815		

Cumulative incidence (%, 95%CI)	36·0 (21·9-50·3)	26·5 (19·8-33·6)		
Cases per 1000 person-years (95%CI)	11·6 (6·6-18·9)	8·7 (6·3-11·8)	0·69 (0·37-1·32)	0·26
Retinopathy §§				
Cases/ Person-years	13/1375	34/4762		
Cumulative incidence (%, 95%CI)	30.2 (16.9-44.6)	22.1 (15.9-29.1)		
Cases per 1000 person-years (95%CI)	9.5 (5.0-16.2)	7.1 (4.9-10.0)	0.71 (0.34-1.48)	0.36
Nephropathy ††				
Cases/ Person-years	1/1473	8/5066		
Cumulative incidence (%, 95%CI)	2·6 (0·2-12·0)	5·1 (2·4-9·4)		
Cases per 1000 person-years (95%CI)	0·7 (0·02-3·8)	1·6 (0·7-3·1)	2·18 (0·28-16·72)	0·45
Neuropathy ‡‡				
Cases/ Person-years	3/1456	4/5073		
Cumulative incidence (%, 95%CI)	6·8 (1·7-17·0)	2·7 (0·9-6·4)		
Cases per 1000 person-years (95%CI)	2·1 (0·4-6·0)	0·8 (0·2-2·0)	0·35 (0·08-1·63)	0·18
CVD Deaths ¶¶				
Cases/ Person-years	12/1473	26/5083		
Cumulative incidence (%, 95%CI)	23·1 (12·6-35·4)	15·2 (10·3-21·0)		
Cases per 1000 person-years (95%CI)	8·2 (4·2-14·2)	5·1 (3·3-7·5)	0·61 (0·36-1·02)	0·062
All-cause Mortality				
Cases/ Person-years	24/1473	50/5083		
Cumulative incidence (%, 95%CI)	41·4 (28·6-53·7)	26·8 (20·6-33·4)		
Cases per 1000 person-years (95%CI)	16·3 (10·4-24·2)	9·8 (7·3-12·9)	0·59 (0·38-0·91)	0·018

Cumulative incidence at 30 years calculated by Kaplan-Meir method.

* HR: Hazard Ratio and P value from Cox proportional hazard models, controlled for clinic randomisation.

§ Diabetes defined from results of the oral glucose tolerance test done every 2 years during the trial (1986–1992), and in 2006 or 2016 at the follow-up examinations, or by self-reported physician-diagnosed diabetes with evidence of elevated glucose levels in the medical record, or receiving hypoglycemic medications.

† CVD events defined as non-fatal or fatal myocardial infarction, or sudden death, hospitalization for heart failure, or non-fatal or fatal stroke.

‡ Stroke defined as non-fatal or fatal stroke.

¶ Coronary heart disease defined as non-fatal or fatal myocardial infarction or sudden death.

‖ Heart failure defined as hospitalization for heart failure.

** Composite microvascular disease defined as an aggregate of retinopathy, nephropathy, or neuropathy.

§§ Retinopathy defined as a history of photocoagulation, blindness from retinal disease, or proliferative retinopathy.

†† Nephropathy defined as a history of end-stage renal disease, renal dialysis, renal transplantation, death from chronic kidney disease (CKD)

‡‡ Neuropathy defined as a history of lower extremity ulceration, gangrene or amputation.

¶ ¶ CVD deaths defined as death due to myocardial infarction, sudden death, heart failure, or stroke.

Table S5. Cumulative Incidence, Incidence Rate and Hazard Ratio for Primary and Secondary Outcome events in Men and Women in the Control and Intervention Groups at the End of the 30-year Follow-up.

	Control Group		Intervention Group		HR* (95%CI) (Intervention/Control)	P value
Men		Person-years =1706		Person-years =5157		
	N	**Rate (95%CI)**	**N**	**Rate (95%CI)**		
All-cause Mortality	52	30·5 (22·8-40·0)	135	26·2 (21·9-31·0)	0·85(0·66-1·09)	0·19
CVD Deaths †	28	16·4 (10.9-23·7)	63	12·2 (9·4-15·6)	0·73 (0·47-1·12)	0·15
Stroke	14	8·2 (4·5-13·8)	34	6·6 (4·6-9·2)	0·79 (0.38-1·63)	0·52
CHD‡	10	5·9 (2·8-10·8)	20	3·9 (2·4-6·0)	0·64 (0·27-1·54)	0·32
Heart Failure	4	2·3 (0·6-6·0)	9	1·7 (0·8-3·3)	0·73 (0·27-1·99)	0.54
Non-CVD Deaths	24	14·1 (9·0-20·9)	72	13·9 (10·9-17·6)	0·98 (0·64-1·52)	0·94
Cancer	8	4·7 (2·0-9·2)	33	6·4 (4·4-9·0)	1·36 (0·67-2·75)	0·39
Infection	9	5·3 (2·4-10·0)	16	3·1 (1·8-5·0)	0·58 (0·29-1·17)	0·13
COPD §	1	0·6 (0·01-3·3)	7	1·4 (0·5-2·8)	2·31 (0·31-17·03)	0·41
Renal failure	1	0·6 (0·01-3·3)	3	0·6 (0·1-1·7)	0·99 (0·13-7·23)	0·99
Diabetes ¶	1	0·6 (0·01-3·3)	3	0·6 (0·1-1·7)	0·99 (0·13-7·23)	0·99
Injury	0	-	4	0·8 (0·2-2·0)	-	-
Cirrhosis	2	1·2 (0·1-4·2)	1	0·2 (0·01-1·1)	0·17 (0·02-1·90)	-
Other ‖	0	-	2	0·4 (0·05-1·4)	-	-
Unknown **	2	1·2 (0·1-4·2)	3	0·6 (0·1-1·7)	0·46 (0·09-2·37)	-
Women		Person-years =1473		Person-years =5083		
All-cause mortality	24	16·3 (10·4-24·2)	50	9·8 (7·3-13·0)	0·59 (0·38-0·91)	0·018
CVD deaths †	12	8·2 (4·2-14·2)	26	5·1 (3·3-7·5)	0·61 (0·37-1·02)	0·062
Stroke	4	2·7 (0·7-7·0)	11	2·2 (1·1-3·9)	0·80 (0·25-2·50)	0·70
CHD‡	6	4·1 (1·5-8·9)	12	2·4 (1·2-4·1)	0·55 (0·21-1·48)	0·24
Heart Failure	2	1·4 (0·2-4·9)	3	0·6 (0·1-1·7)	0·42 (0·10-1·77)	0.24
Non-CVD deaths	12	8·2 (4·2-14·2)	24	4·7 (3·0-7·0)	0·56 (0·22-1·43)	0·23
Cancer	6	4·1 (1·5-8·9)	10	2·0 (0·9-3·6)	0·48 (0·19-1·22)	0·12
Infection	2	1·4 (0·2-4·9)	3	0·6 (0·1-1·7)	0·42 (0·05-3·30)	0·41
COPD §	1	0·7 (0·02-3·8)	1	0·2 (0.005-1·1)	0·29 (0·03-3·33)	-
Renal failure	0	-	5	1·0 (0·3-2·3)	-	-
Diabetes ¶	1	0·7 (0·02-3·8)	2	0·4 (0·05-1·4)	0·56 (0·05-6·07)	-
Injury	0	-	1	0·2 (0·005-1.1)	-	-
Cirrhosis	0	-	0	-	-	-
Other ‖	0	-	1	0·2 (0·005-1·1)	-	-
Unknown **	2	1·4 (0·2-4·9)	1	0·2 (0·005-1·1)	0·13 (0·02-1·07)	-

* HR: Hazard Ratio and P value from Cox proportional hazard models, controlled for clinic randomisation.

† CVD deaths defined as death due to myocardial infarction, sudden death, heart failure, or stroke.

‡ CHD: Death from coronary heart disease (myocardial infarction or sudden death).

§ COPD: Chronic obstructive pulmonary disease.

¶ Diabetes: Death from ketoacidosis, or hyperosmolar coma.

‖ Other: including bleeding of upper digestive tract, or multi-organ failure.

**Unknown: unknown causes.

Table S6. Cause-specific Death Rates (per 1000 person-years) in Men and Women in the Control and Intervention Groups at the End of the 30-year Follow-up.

	Smokers		Non-smokers	
	HR* (95%CI)	**P value**	**HR* (95%CI)**	**P value**
Men	n =193 (61·9%)		n =119 (38·1%)	
Diabetes	0·49 (0·36-0·68)	<0.0001	0·83 (0·49-1·41)	0·50
CVD events	0·80 (0.56-1·13)	0·20	0·79 (0·58-1·08)	0·14
Composite Micro	0·45 (0.23-0·89)	0.02	0·88 (0·31-2·50)	0·81
CVD death	0·94 (0·46-1·91)	0.86	0·51 (0·30-0·87)	0·01
All-cause death	0·92 (0·70-1·21)	0.57	0·76 (0·46-1·24)	0·27
Women	n =45 (17·0%)		n =219 (83·0%)	
Diabetes	0·75 (0·43-1·30)	0·30	0·61 (0·40-0·93)	0·02
CVD events	0·71 (0·32-1·58)	0·40	0·72 (0·51-1·02)	0·07
Composite Micro	2·34 (0·73-7·47)	0·15	0·53 (0·27-1·06)	0·07
CVD death	0·82 (0·27-2·51)	0·73	0·62 (0·33-1·19)	0·15
All-cause death	1·07 (0·35-3·22)	0·91	0·53 (0·32-0·87)	0·01
Both sexes	n =238 (41·3%)		n =338 (58·7%)	
Diabetes	0·63 (0·47-0·84)	0·001	0·68 (0·46-1·01)	0·058
CVD events	0·79 (0·56-1·12)	0·18	0·74 (0·58-0·94)	0·015
Composite Micro	0·70 (0·42-1·17)	0·18	0·63 (0·33-1·20)	0·16
CVD death	0·92 (0·50-1·71)	0·80	0·55 (0·33-0·92)	0·022
All-cause death	0·96 (0·72-1·28)	0·78	0·64 (0·49-0·84)	0·001

*HR: Hazard Ratio (Intervention/Control) and P value from Cox proportional hazard models, controlled for clinic randomisation.

Table S7. Effect of lifestyle Intervention on Primary Outcome events in Smoking and Non-smoking Participants.

	Controlled for Clinic-randomisation		Controlled for Clinic-randomisation and Smoking	
	HR*(95%CI)	**P value**	**HR*(95%CI)**	**P value**
Men				
Diabetes	0·61 (0·44-0·83)	0·0018	0·61 (0·44-0·84)	0·0023
CVD events	0·80 (0·60-1·06)	0·12	0·79 (0·59-1·06)	0·12
Composite MICRO	0·61 (0·35-1·06)	0·081	0·59 (0·34-1·03)	0·062
CVD Death	0·73 (0·47-1·12)	0·15	0·71 (0·46-1·10)	0·13
All-cause Death	0·85 (0·66-1·09)	0·19	0·86 (0·68-1·10)	0·23
Women				
Diabetes	0·62 (0·42-0·92)	0·017	0·63 (0.42-0.95)	0·025
CVD events	0·69(0·51-0·92)	0·013	0·71 (0·53-0·95)	0·023
Composite MICRO	0·69 (0·37-1·32)	0·26	0·78 (0·38-1·62)	0·51
CVD Death	0·61 (0·37-1·02)	0·062	0·67(0·40-1·12)	0·13
All-cause Death	0·59 (0·38-0·91)	0·018	0·66(0·41-1·06)	0·08
Both Sexes				
Diabetes	0·61 (0·45-0·83)	0·0015	0·61(0·44-0·83)	0·0015
CVD events	0·74 (0·59-0·92)	0·006	0·76(0·62-0·93)	0·008
Composite MICRO	0·65 (0·45-0·95)	0·025	0·66(0·44-0·97)	0·069
CVD Death	0·67 (0·48-0·94)	0·022	0·70(0·51-0·97)	0·036
All-cause Death	0·74 (0·61-0·89)	0·0015	0·81(0·66-0·99)	0·036

*HR: Hazard Ratio (Intervention/Control) and P value from Cox proportional hazard models.

Table S8. Comparison of Hazard Ratios for Primary Outcome Events before and after correcting for Smoking.

Treatment	Control	Intervention	P value
	N (%)	N (%)	
Any glucose lowering agent	72(80·0 %)	219(77·4%)	0·60
No glucose- lowering agents	18(20·0%)	64(22·6%)	
Insulin	64(74·4%)	164(60·1%)	0·02
No insulin	22(25·6%)	109(39·9%)	
Oral agents	38(45·8 %)	125(46·3 %)	0·93
No oral agents	45(54·2%)	145(53·7%)	
Blood pressure lowering agents	55(64·7%)	189(69·5%)	0·41
No BP-lowering agents	30(35·3%)	83(30·5%)	
Statins	36(44·4%)	107(42·3 %)	0.73
Not taking statins	45(55·6%)	146(57·7%)	
Aspirin	33(44·0%)	119(51·5%)	0·26
Not taking aspirin	42(56·0%)	122(48·5%)	

Table S9. Treatment with Glucose-, Blood Pressure-, Lipid-lowering Agents, and Aspirin in Control and Intervention Groups.

	Cases/ Person-years	Cumulative incidence (%, 95%CI)	HR*(95%CI)
Diabetes§			
Control**	126/1072	95·94 (89·11-98·52)	
Diet §§	113/1534	89·62 (81·.22-94·39)	0.75 (0.56-1.001)
Exercise ††	112/1911	83·25 (74·88-89·04)	0.60 (0.44-0.82)
D&E ‡‡	112/1320	94·15 (86·70-97·49)	0.77 (0.55-1.08)
CVD events†			
Control	80/2715	66·52(57·03-74·38)	
Diet	65/2985	54·13(44·51-62·79)	0·72 (0·54-0·97)
Exercise	73/3045	54·46(45·42-62·64)	0·81 (0·61-1·06)
D&E	57/2746	49·71(40·08-58·60)	0·68 (0·52-0·90)
Composite Microvascular Disease‡			
Control	33/2974	34·04(24·51-43·80)	
Diet	25/3234	24·29(16·35-33·09)	0·66 (0·42-1·02)
Exercise	32/3446	30·32(21·55-39·53)	0·80 (0·50-1·27)
D&E	19/3091	20·00(12·57-28·68)	0·50 (0·33-0·76)
CVD Deaths¶			
Control	40/3179	35·23(26·37-44·20)	
Diet	29/3386	25·49(17·73-33·95)	0·67 (0·46-0·97)
Exercise	37/3640	29·34(21·56-37·55)	0·80 (0·51-1·24)
D&E	23/3214	21·66(14·31-30·02)	0·54 (0·30-0·97)
All-cause Deaths			
Control	76/3179	56·26(47·42-64·18)	
Diet	63/3386	46·35(37·73-54·52)	0·77 (0·61-0·97)
Exercise	71/3640	49·08(40·66-56·97)	0·81 (0·63-1·04)
D&E	51/3214	40·31(31·69-48·75)	0·64 (0·48-0·84)

Cumulative incidence at 30 years calculated by Kaplan-Meir method.

* HR: Hazard Ratio and P value from Cox proportional hazard models, controlled for clinic randomisation.

§Diabetes defined from results of the oral glucose tolerance test done every 2 years during the trial (1986–1992), and in 2006 or 2016 at the follow-up examinations, or by self-reported physician-diagnosed diabetes with evidence of elevated glucose levels in the medical record, or receiving hypoglycemic medications.

† CVD events defined as non-fatal or fatal myocardial infarction, sudden death, hospitalization for heart failure, or non-fatal or fatal stroke.

‡Composite microvascular disease defined as an aggregate of retinopathy, nephropathy, or neuropathy.

¶ CVD deaths defined as death due to myocardial infarction, sudden death, heart failure, or stroke.

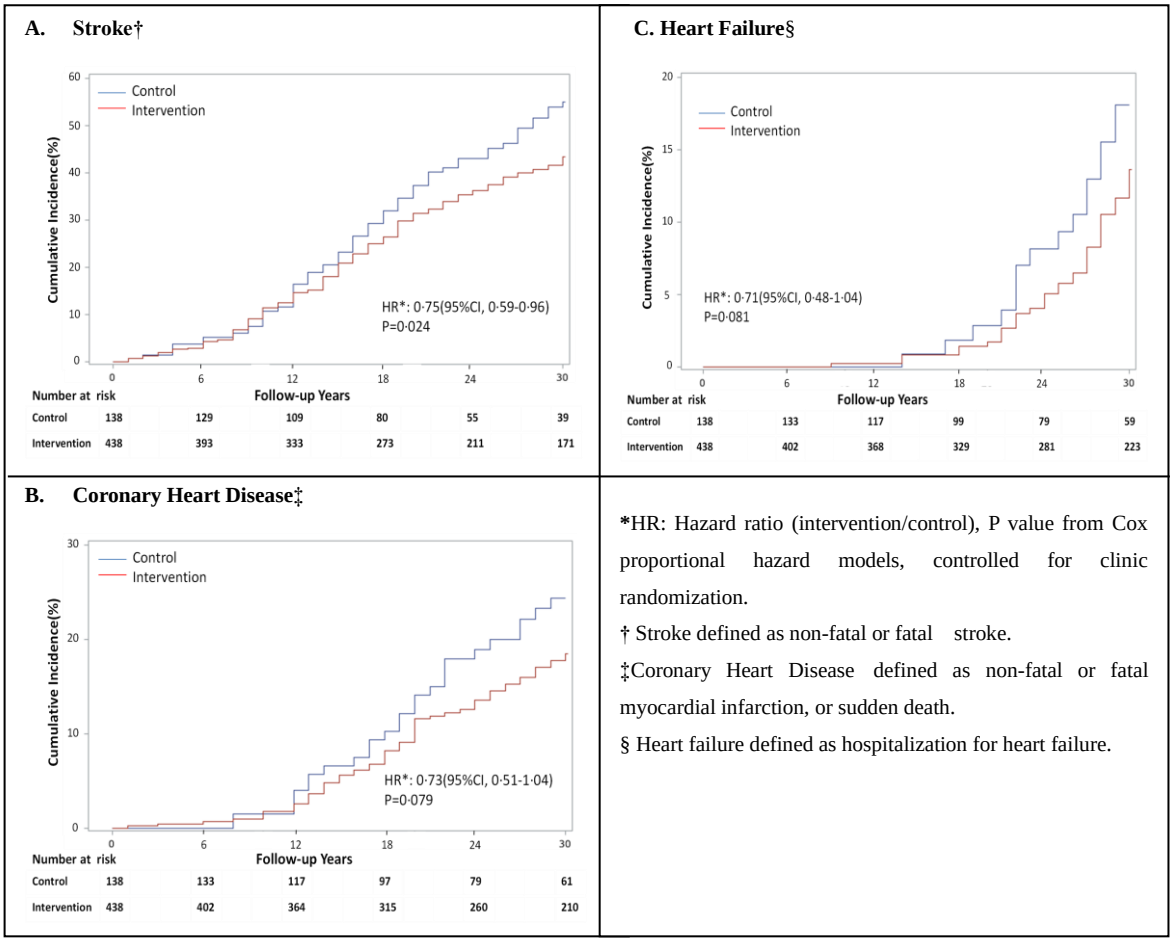
**Control participants were given brochures with general instructions for diet and/or increased leisure physical activities only. No individual instruction or formal group counseling sessions were given.

§§ Participants in the Diet only clinics had group counseling sessions at 1 month, monthly for 3 months, and then once every 3 months for the remainder of the 6-year intervention period. Those with BMI<25 kg/m^2 were (1) prescribed a diet containing 25-30 kcal/kg body weight (105-126kj/kg), 55-65% carbohydrate, 10-15% protein, and 25-30% fat and (2) encouraged to consume more vegetables, reduce alcohol intake and consume less simple sugars. Those with BMI of 25 kg/m^2 or over were asked to (1) lower calorie intake to lose 0.5-1.0 kg body weight per month until they achieved a BMI of 23 kg/m^2, and (2) set personal goals for total calorie consumption and for daily quantities of cereals, vegetables, meat, milk, and oils.

†† Participants in Exercise only clinics received group counseling sessions at 1 month, monthly for 3 months, and then once every 3 months for the remainder of the 6-year intervention period. They were asked to increase their leisure physical activity by at least 1unit/day, and more units for the younger and those without CVD or arthritis. One unit of exercise was either 30-minutes of mild exercise (e.g. slow walking), 20 minutes of moderate exercise (e.g. fasting walking), or 10-minutes of strenuous exercise (e.g. slow running), or 5-mininutes of very strenuous exercise (e.g. playing basketball).

‡‡Clinics in the Dietary plus Exercise intervention arm provided instructions and counseling for both diet and exercise interventions that were similar to those for the diet-only and the exercise only intervention groups.

Table S10. Cumulative Incidence and Hazard Ratios for Primary Outcome Events in the Control, Diet, Exercise, and Diet and Exercise (D&E) sub-groups at the end of the 30-year Follow-up.



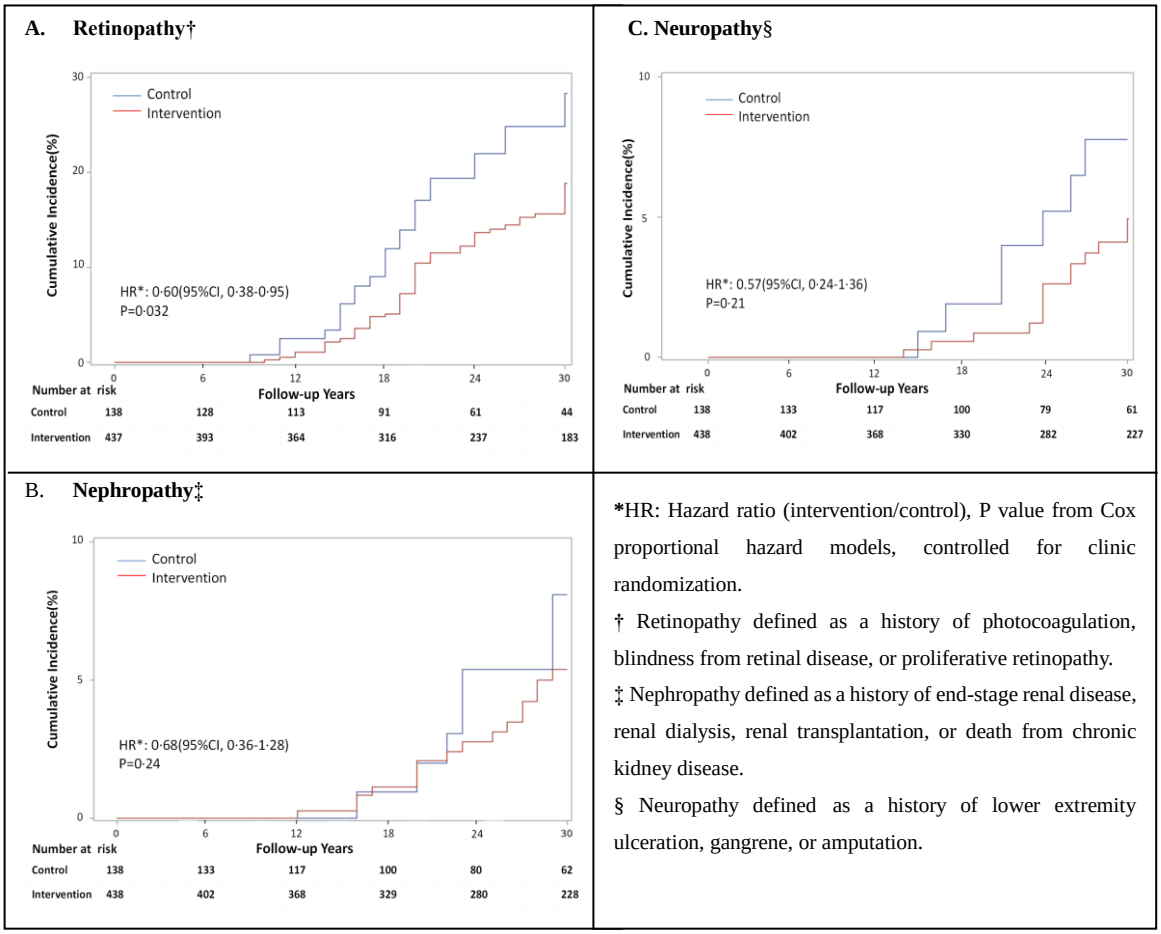
***HR: Hazard ratio (intervention/control), P value from Cox proportional hazard models, controlled for clinic randomization.

† Stroke defined as non-fatal or fatal stroke.

‡Coronary Heart Disease defined as non-fatal or fatal myocardial infarction, or sudden death.

§ Heart failure defined as hospitalization for heart failure.

Figure S1. Kaplan-Meier Plot of Cumulative Incidence of Cardiovascular Disease: Stroke (Panel A), Coronary Heart Disease (Panel B), and Heart Failure (Panel C) in the Control and Intervention Groups during the 30-year Follow-up.



*****HR: Hazard ratio (intervention/control), P value from Cox proportional hazard models, controlled for clinic randomization.

† Retinopathy defined as a history of photocoagulation, blindness from retinal disease, or proliferative retinopathy.

‡ Nephropathy defined as a history of end-stage renal disease, renal dialysis, renal transplantation, or death from chronic kidney disease.

§ Neuropathy defined as a history of lower extremity ulceration, gangrene, or amputation.

Figure S2. Kaplan-Meier Plot of Cumulative Incidence of Microvascular Disease: Retinopathy (Panel A), Nephropathy (Panel B), and Neuropathy (Panel C) in the Control and Intervention Groups during the 30-year Follow-up.

Sources and Availability of Data for the Outcome Study.

The original Da Qing Diabetes Prevention Study (DQDPS)[1] was a six-year cluster-randomised trial to determine the effect of three different lifestyle interventions on the incidence of diabetes in people with IGT. Participants with IGT, aged 25 to 74 years, identified from screening 110,600 Da Qing residents, were randomised by clinic into four approximately similar sized groups who then received dietary, exercise, or diet+exercise interventions for six years, or as a comparison (control) group. During the trial, participants were examined at the baseline and at two-yearly intervals, and received 75g oral glucose tolerance tests at these examinations. The trial began in 1986 and ended in 1992. The only primary outcome of the trial was the six-year cumulative incidence of diabetes in each of the three intervention groups vs. the control group.

The Da Qing Diabetes Prevention Outcome Study (DQDPOS) was designed and initiated in 2006 with the goal of determining if the earlier intervention influenced the development of diabetes-related complications.[2] As each of the three individual trial intervention groups had shown similarly reduced diabetes incidence but had limited sample size, for the DQDPOS these groups were combined a priori into a single intervention group. This provided a sample size sufficient to provide the statistical power needed to detect differences in outcomes between those exposed to the intervention and the control group. We attempted to contact all previous participants of the DQDPS to determine their vital status as of December 31st 2016, and invite those still alive to participate in follow-up examinations. The study had predefined primary and secondary outcomes relating to the complications of diabetes. For deceased participants, information was obtained from proxy informants, a living spouse, sibling, or child, using standardized questionnaires and verified by review of medical records and/or death certificates. In the 2006 follow-up data on mortality were obtained for 542 (94.1%) of the original trial participants and relevant information on 372 (93.0%) of the 400 living participants.

The 2009 DQDPOS goal was update and collect mortality, cause of death and medical record data from participants who had died since the 2006 follow-up study.[3] No interviews or examinations were conducted among those still alive.

In the 2016 DQDPOS, vital status was determined in all participants not previously known to be deceased. The primary and secondary outcomes were predefined, and as in the 2006 follow-up, information on deceased participants was obtained from proxy informants, a living spouse, sibling, or child, using standardized questionnaires and verified by review of death certificates and medical records. Among the 279 still alive, 231 (82.8%) were interviewed and reexamined.

1. Pan XR, Li GW, Hu YH, et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and Diabetes Study. Diabetes Care 1997; 20(4): 537-44.

2. Li G, Zhang P, Wang J, et al. The long-term effect of lifestyle interventions to prevent diabetes in the China Da Qing Diabetes Prevention Study: a 20-year follow-up study. Lancet 2008; 371(9626): 1783-9.

3. Li G, Zhang P, Wang J, et al. Cardiovascular mortality, all-cause mortality, and diabetes incidence after lifestyle intervention for people with impaired glucose tolerance in the Da Qing Diabetes Prevention Study: a 23-year follow-up study. Lancet Diabetes Endocrinol 2014; 2(6): 474-80.

Summary of Sources and Availability of Data for the Outcome Study*.

	Control Group		Intervention Group		
	No.	Percent	**No.**	Percent	**Total**
In 1986 Original sample size	138	(100%)	438	(100%)	576
In 1992					
No. evaluated for diabetes	133	(96·4%)	397	(90·6%)	530
In 2006					
No. with 20-year follow-up data	135	(97·8%)	407	(92·9%)	542
Deaths (death certificates, proxy interviews and medical records)	40	(29·6%)	102	(25·1%)	
Alive on Dec 31st 2006	95	(70·3%)	305	(74·9%)	
No. examined	87	(64·4%)	285	(70·0%	
With Retinal examination	75/95	(78·9%)	238/305	(78·0%)	
Urinary A/C ratio	79/95	(83·2%)	254/305	(83·3%)	
Monofilament test	79/95	(83·2%)	254/305	(83·3%)	
In 2009					
No. with 23-year follow-up data	135	(97·8%)	407	(92·9%)	542
Deaths (death certificates, proxy interviews and medical records)	53	(39·3%)	121	(29·7%)	
Alive on Dec 31st 2009	82	(60·7%)	286	(70·3%)	
In 2016*					
No. with 30-year follow-up data	135	(97·8%)	405	(92·5%)	540
Deaths (death certificates, proxy interviews and medical records)	76	(56·3%)	185	(45·7%)	
Alive on Dec 31st 2016	59	(43·7%)	220	(54·3%)	
No. examined	48/59	(81·4%)	183/220	(83·2%)	
With Retinal examination	36/59	(61·0%)	143/220	(65·0%)	
Urinary A/C ratio	42/59	(71·2%)	169/220	(76·8%)	
Serum creatinine	45/59	(76·2%)	178/220	(80·9%)	
Monofilament test	47/59	(79·7%)	173/220	(78·6%)	

*In the follow-up studies data were obtained for some participants who earlier had been reported as 'lost to follow-up'.

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2016 STUDY PROTOCOL

Thirty-year Follow-up of the Da Qing Diabetes Prevention Outcome Study

Study Protocol Version 1.0

6/22/2016

1. **Title of Project:** Thirty-year Follow-up of the Da Qing Diabetes Prevention Outcome Study

2. **Summary**

Diabetes has become a major public health crisis in China and the US. In China, more than one in ten adults have diabetes, amounting to more than 100 million people with the disease—more than any other country in the world and in 2010 in the US, 26 million Americans lived with diabetes. Furthermore, as many 50% of adults in China and 79 million people in the US had pre-diabetes. Thus the diabetes crisis will only worsen if no prevention actions are taken.

The design of diabetes prevention strategies needs knowledge of the short-term and long-term health benefits of preventive interventions. The Da Qing Diabetes Prevention Study (DQDPS) in China was the first randomized clinical trial in the world to test the hypothesis that structured lifestyle interventions applied to people with impaired glucose tolerance (IGT) can prevent type 2 diabetes. DQDPS randomized 577 people with IGT by clinics into either a control condition or one of three lifestyle conditions (diet, exercise, diet + exercise). The study, which began in 1986, showed that interventions with diet, exercise, and diet plus exercise carried out over a six-year period could reduce risk of developing diabetes by a 33%, 47%, and 38%, respectively, compared to the control group. DQDPS began 8-10 years earlier than the two major similar trials in Finland and United States.

Two follow-up studies (at 20-years and 23-years) were conducted after the end of the active intervention phase of DQDPS. The follow-up studies examined the long-term effect of the life-style intervention tested in DQDPS on the incidence of diabetes, cardiovascular disease (CVD), diabetes related microvascular and other macrovascular complications and all-cause and CVD mortality. The follow-up studies showed that reduced diabetes incidence seen during the 6-year period of active intervention persisted for more than two decades. The combined lifestyle intervention was associated with a 47% reduction in the incidence of severe retinopathy, a 41% reduction in CVD mortality, and a 29% reduction in all-cause mortality. However, the incidence of the first nonfatal or fatal cardiovascular events including myocardial infarction, sudden death, stroke, or amputation did not significantly differ between the combined intervention and the control groups, mainly due to the small number of events, which limit the statistical power to detect the group difference for those outcomes. Thus, whether the lifestyle intervention can reduce the risk of those complications remains unclear, but as the study participants get older, both complication and mortality rates will accelerate.

The proposed 30-year follow-up study is to take the advantage of opportunity provided by the study cohort to determine whether lifestyle intervention can reduce the incidence of CVD and other long-term diabetes complications such as amputation and renal failure.

3. Study background

Diabetes has become a major public health problem in China and the US. In China, more than one in ten people have diabetes, amounting to more than 100 million adults with the disease—more than any other country in the world. In 2010, the estimated health care expenditure attributable to diabetes was over 50 billion US dollars. In the US, nearly 26 million Americans lived with diabetes in 2010. Diabetes has also become a substantial drain on the American economy, with 245 billion dollars in medical costs and loss in productivity in 2012. In addition, in 2010 as many as 50% of adults in China and 79 million people in the US had pre-diabetes, a condition where blood glucose levels are higher than normal, but not quite high enough to be considered diabetes. The International Diabetes Federation projects that number of persons with diabetes and the health and economic burdens associated with the disease will continue to increase in both countries and the world. Primary prevention is an essential way to slow the future increase in diabetes incidence and reverse the trend.

The design and implementation of diabetes prevention strategies needs knowledge of the short-term and long-term health benefits of various preventive interventions. Da Qing Diabetes Prevention Study (DQDPS) in China was the earliest randomized clinical trial in the world to test the hypothesis that structured lifestyle interventions applied to people with impaired glucose tolerance (IGT) can prevent type 2 diabetes. DQDPS randomized 577 people with IGT by clinics into either a control condition or one of three lifestyle conditions (diet, exercise, diet plus exercise). The study showed after six years that interventions with diet, exercise, and diet plus exercise could reduce risk of developing diabetes by a 33%, 47%, and 38%, respectively, compared to the control group.

DQDPS is a landmark study in advancing the science of utilizing lifestyle intervention for the prevention of diabetes. In addition to having been conducted 8 to 10 years earlier than the other two major diabetes prevention studies completed in western populations (the Finnish Diabetes prevention study, DPS, and the US Diabetes Prevention Program, DPP), DQDPS has several other unique aspects. First, it was conducted in an Asian population. Second, the population was considerably leaner than in the Finnish and U.S. studies, yet the study found benefits of lifestyle change regardless of body mass index (BMI). Third, DQDPS randomized entire clinics/health centers to intervention, as opposed to individual-level randomization, as was done in the other studies. Fourth, interventions used were less intense, but closer to those which can be carried out in a community setting. Finally, the study separately tested the effectiveness of diet and exercise whereas the other major diabetes prevention studies tested only combined diet and exercise regimens.

Two follow-ups have been conducted since the end of the DQDPS. The 20-year follow-up study started in 2003. The primary objectives of the study were to examine the long-term effect of the intervention tested in DQDPS on rates of diabetes incidence, cardiovascular disease (CVD) incidence and mortality, all-cause mortality, and any diabetes related microvascular or macrovascular complications. Results from the 20-year follow-up study showed that the reduction in diabetes incidence seen during the 6-year period of active intervention persisted for two decades. The lifestyle intervention groups had a 43% lower diabetes incidence rate for up to 14 years after the active intervention ceased, and diabetes onset was delayed an average of 3.6 years. The incidence of the first nonfatal or fatal cardiovascular events including myocardial infarction, sudden death, stroke, or amputation and all-cause mortality did not significantly differ between the combined intervention group and the control group. The death from CVD was 17% lower in the intervention group but this difference was not statistically significant. The lifestyle intervention was associated with a 47% reduction in the incidence of severe, vision-threatening retinopathy, but such beneficial effects were not seen for nephropathy or neuropathy.

The 23-year follow-up, conducted in 2009, extended the first follow-up for a further three years. The

main focus of the study was to examine the long-term effect of the intervention tested in DQDPS on the CVD and all-cause mortality. Additional Information on diabetes related microvascular and microvascular complications were not collected due to lack of resources for the data collection. The findings of the 23-year follow-up showed the lifestyle intervention was associated with a statistically significant 41% reduction in CVD mortality and 29% reduction in all-cause mortality. In addition, the study also demonstrated that the benefit of the lifestyle intervention in reducing diabetes incidence was extended up to 23 years.

The findings from the DQDPS and the subsequent follow-up studies have expanded our scientific knowledge on both the short-term and long term health impacts of lifestyle interventions to prevent or delay diabetes in persons with IGT. Those findings also have had a tremendous impact in diabetes guiding public health strategy for diabetes prevention. However, important research questions remain unanswered about the long-term effect of diabetes prevention efforts on diabetes-related microvascular and macrovascular complications and other health outcomes such as health related quality of life, aged-related health outcomes such as functional limitation and life expectancy. The answers to those remaining questions will play a critical role in policy decisions whether lifestyle intervention is the most efficient way to combat the diabetes pandemics in both China and the US as well as worldwide.

A main barrier that limits the ability of the two follow-ups of DQDPS from answering these remaining questions well is the low rate of development of diabetes-related complications in the study population during the follow-up period. This is not surprising as many of the serious complications related to diabetes only appear after many years duration of diabetes. To date the small number of events in terms of both complications and mortality have limited the statistical power to assess differences in these outcomes between the intervention groups and control group. For the same reasons, other diabetes prevention studies such as Finnish Diabetes Prevention Study and US Diabetes Preventions Program, while confirming the effect of lifestyle interventions in delaying the onset of diabetes for up to at least ten years, have so far been unable to answer questions related to rates of complications and mortality. As the study participants become older and the duration of diabetes increases, both complications and mortality rates will accelerate. Thus further follow-up, with longer follow-up time and longer durations of diabetes, will yield the higher numbers of events that are needed to determine if the reduction in diabetes incidence produced by the lifestyle intervention translates into differences in the serious diabetes-related complications. DQDPS can answer the questions 8-10 years earlier than other major diabetes prevention trials in Finland and United States. In addition, the proposed 30-year follow-up also provides an opportunity to examine the effect of the lifestyle intervention on additional health outcomes such as health related quality of life and functional limitations, which were not included in the previous follow-up studies due to lack of resources and relative low rates of occurrences (e.g., aged related health outcomes such as mobility limitations).

4. Study objectives

The primary objectives of the 30-year follow-up DQDPS are to examine the long-term influence of the intervention as implemented in the original DQDPS on rates of (1) major CVD events, including fatal and nonfatal myocardial infarction, fatal and nonfatal stroke, or other cardiovascular death (2) composite diabetes-related micro-vascular complications, including nephropathy, retinopathy and neuropathy, (3) life expectancy, and (4) complication free years.

Secondary objectives are to evaluate the effects of interventions on (1) physical functional limitations, (2) cognitive functional limitations, (3) specific microvascular complications (retinopathy, neuropathy, or nephropathy), (4) specific macrovascular complications (myocardial infarction, stroke, heart failure), (5) overall health related quality of life, (6) all-cause mortality, (7) CVD mortality and (8) diabetes incidence.

For some outcomes, either primary or secondary, if current evidences point to a difference by sex such as life expectancy, rate of all-cause or CVD mortality, the long-term effect of the lifestyle intervention will be assessed separately for men and women.

5. Study Population

The 30-year follow-up of DQDPS will consist of a longitudinal follow-up of each of the 393 participants who were still alive in the 23-year follow-up of DQDPS. This include re-contacting them or their proxies to know their survival status. For those who are alive, their informed consent is also needed for a detailed health examination, including physical and laboratory measurements, medical record reviews, and interviews to assess study outcomes. We will also conduct a hospital record review, and with informed consent, proxy interviews for patients who have died since 2009 to determine their causes of death and presence of diabetes and related complications up to the time of their death.

6. Study Interventions

Interventions used in the original DQDPS, i.e., one of three lifestyle conditions (diet, exercise, diet plus exercise) and control group.

7. Study Outcomes

Primary outcomes

(1) Major CVD events
   a. fatal and nonfatal myocardial infarction
   b. fatal and nonfatal stroke
   c. other cardiovascular death

(2) Composite of microvascular diseases
   a. Nephropathy: increased albuminuria (≥30 mg/gram creatinine), or renal dysfunction (end-stage renal disease, dialysis or renal transplant) or eGFR ≤ 60 ml per min based on serum creatinine, using the CKD-EPI equation or another validated algorithm),
   b. Retinopathy: retinopathy by fundus photography (ETDRS grade of ≥30) or adjudicated history of laser or other treatment for retinopathy, or
   c. Neuropathy: reduction or absence of light touch sensation to monofilament (Semmes-Weinstein 10 gram) in either foot (< 8 of 10 applications detected).

(3) Life expectancy: the average cumulative life years over the 30- year study period

(4) Complication free years: life years without any diabetes-related complications.

Secondary outcomes

- Further development of diabetes

- Diabetic retinopathy
- Diabetic neuropathy
- Diabetic nephropathy
- Cardiovascular disease events
- Risk factors for cardiovascular disease
- Amputation in a lower extremity not resulting from major trauma
- Physical functional limitations
- Cognitive and memory related outcomes
- Quality of life
- All-cause mortality
- CVD mortality
- Diabetes-related mortality, defined any death related CVD, ESRD, infections, diabetic ketoacidosis, and hypoglycemia coma.
- Cancer mortality
- Other aged related outcomes such as osteoporosis

8. Data collection

Major steps in the data collection of the 30-year follow-up of DQDPS will be similar to those used in the previous follow-up studies and are as follows: (1) Recruitment of living participants for health examinations, interviews, and medical record review; (2) data collection through proxy interview and hospital records for deceased participants.

Although diabetes incidence is not a primary outcome in this phase of the study, information on diabetes status of the study participants is essential for understanding the mechanism of the intervention effect on the primary outcomes. For persons not already known to have diabetes, an oral glucose tolerance test is needed to establish his/her diabetes status, in which the subject will be asked to fast for 12 hours before the visit, to eat normally for 3 days before the visit and avoid heavy exercise on the day before the visit. The subjects with previously diagnosed diabetes mellitus will have all other measurements except the oral glucose tolerance test (fasting plasma glucose, serum insulin and HbA1c will be measured). Both the physical examination and personal interview will be conducted in a central location (i.e., Da Qing General Hospital) if possible.

A home visit may be needed if a subject has difficulty in coming for the examination. Potential subjects for home visit include those (1) who are not able to come to the examination center due to poor health conditions (2) who moved away from the Da Qing area. Home visits will be conducted only if the physical examination and interview in Da Qing General Hospital are not possible. Persons who will perform the home visit will be restricted to a few members of the medical staff who are certified to assess the listed outcomes.

Physical examination and personal interview during a home visit should follow the procedure used during an invited clinical visit as closely as possible. A proxy should be used if the subject has a difficulty to answer the interview questions. The blood sample collected during a home visit should follow the standard procedure used for the hospital-based examinations. A local hospital or clinic should be chosen to perform the physical examination and personal review if more than two subjects live in the same area outside of Da Qing. Based on the previous follow-up studies, we anticipate that very few of the participants will have left Da Qing.

For those participants whose health condition does not permit a physical examination or/and personal interview, we will rely on secondary sources to collect the data needed by the study. If a proxy can be identified and agrees to participate, we will interview the proxy and ask the same questions as asked of the participants. For clinical and bio-chemical measures that would be collected in the physical examination, we will rely on information contained in their clinical and hospital records. The study participant will be considered as 'lost to follow-up' if the above effort fails. A study steering committee will be established and this committee will ensure the safety of study participants.

Table 1. Summary of the main data elements and the sources

Variable	Death Certificate	Medical Record review	Proxy interview	Interview	Health Examination	
					Physical Exam	Laboratory
Primary Outcomes						
Coronary heart disease	X	X	X	X	X (EKG) Angiography	
Stroke	X	X	X	X	X	Intimal-medial Thickness
Cardiovascular surgery	X	X	X	X		
End stage renal disease	X	X	X	X		Serum Creatinine
Diabetic nephropathy	X		X	X	X	Serum Creatinine; Urine A/C ratio
Diabetic retinopathy	X				X	Retinal photos
Blindness	X	X	X	X	X (visual acuity)	
Peripheral vascular disease	X	X	X	X	X(ABI), ulcer	
Coronary heart disease	X	X	X	X	X (ECG)	
Congestive heart failure	X	X	X	X	X	
Life expectancy (mortality)	X	X	X			
		X				
Secondary outcomes		X	X	X		

Physical functional limitations				X	X	walking/balance tests.
Cognitive, memory related out comes		X	X	X		Memory test
All-cause Mortality	X	X	X			
CVD mortality	X	X	X			
Diabetes-related death	X	X	X			
Cancer death	X	X	X			
Other causes of death	X	X	X			
Diabetes		X	X	X		X (OGTT//HbA1c)
Blood pressure		X			X	
Lipid tests and renal test		X				Serum creatinine, Urine A/C ratio
Weight					X	
Health related quality of life				X (EuroQoL)		
Bone Density						Dual Energy X-ray absorption (DEXA)

A medical record review will be conducted in order to determine the selected diabetes complications (see items in the primary and secondary outcomes). Regulations in China do not call for consent to access medical records of a deceased person for the purpose of medical research. Therefore, no consent form is needed for accessing the health records of persons who are dead. We will go to both the local health clinic where the study participant obtained his or her routine medical care and the two hospitals in Da Qing city (there are only two hospitals in Da Qing) to get a copy of all the medical records for the participants. Then, we will abstract the outcome or events needed (see the data summary table). We expect that we can collect medical records for over 80% of the participants. Procedures used to safeguard the collected information are described in the data storage section. Second, for participants lacking medical records, the similar information will be obtained through a proxy interview. To evaluate the comparability of the two data sources, we will also conduct the proxy interview for a number of the participants for whom we have a medical record, using the same interview questionnaire.

The medical record review and/or proxy interviews will be conducted to determine whether the deceased participant had any of the diabetes related complications as described in primary and secondary outcomes and if yes, date of recognition should be recorded. The events recorded are

regarded as end-points.

9. Definition of the study outcome

Specific definitions of the primary and secondary study outcomes are described below.

Table 2. Definitions of Primary and Secondary Study Outcomes:

Primary Outcomes	**Definition**
Coronary heart disease	Coronary heart disease, defined by fatal and non- fatal myocardial infarction, or silent myocardial infarction base on EKG, coronary artery stenosis (50% documented by angiography), or coronary revascularization.
Stroke	Stroke or carotid endarterectomy, defined by self-report, hospital record, or proxy
Congestive heart failure	Congestive heart failure needed to be hospitalized
Peripheral arterial disease	Ankle brachial index < 0.9 or ≥ 1.3, intermittent claudication based on interview. Foot ulcer
Diabetic nephropathy	serum creatinine and albuminuria (Urinary Alb/Cr ratio)
Retinopathy	ETDRS grade of ≥30
Nephropathy	albuminuria (≥30 mg/gram creatinine) or renal dysfunction (creatinine >2 mg/dL), or transplantation or dialysis .
Neuropathy	≥ 8 insensate sites out of 10 (5 sites tested on each foot)
Amputation	Any low extremity amputations that were clearly not associated with major trauma
Life expectancy	Average cumulative life years over the 30- year study period, Calculated as the sum of the average survival probability by study arm.
Complication free years	Complication free years is calculated as the average cumulative year without any diabetes-related complications during the 30-year study period. Diabetes-related complications include any of the diabetes-related macro- and micro- complications.
Physical functional limitations	Activity of Daily Living (ADL) Mobility, motion, balance, or gait speed, manual dexterity and physical strength
Cognitive, memory related out comes	Cognitive functions and Memory test. Dementia
Health-related quality of life	EuroQol Questionnaire
All-cause mortality	Death from any causes
CVD mortality	CVD mortality – (base on ICD-10 codes)
Cancer mortality	Cancer mortality- (base on ICD-10 codes)
Diabetes related mortality	death related CVD, ESRD, infections, diabetic ketoacidosis, and hypoglycemia coma
Diabetes	Fasting plasma glucose level of 126 mg/dL [7.0 mmol/L] or 2-hour plasma glucose level of 200 mg/dL [11.1 mmol/L], after a 75 gram

	OGTT.
Risk factors for CVD	Blood pressure (130/85mmHg), lipids (define), waist circumference, HbA1c, smoking
Other aged related outcomes	DEXA for bone density

10. Determination and adjudication of causes of death

11. Data management

Data from patient and proxy interview, patient medical chart reviews, laboratory tests and physical examinations will be entered in paper forms first and then transferred onto pre-defined electronic forms. Two persons from the study group will be appointed as the data mangers: one in the Da Qing area and the other in China-Japan Friendship hospital and each will be responsible for data collected in each site. The two data managers will be trained and certified to verify and rectify the accuracy and completion of data collection forms. Quality assurance software will be implemented, which will check range parameters, internal consistencies, and flag suspicious values for review. If data assurance requirements are not met, the software will not accept the entry as complete. The data manager will then review the problem and take corrective action as specified in the manual of operations or as instructed by the steering committee. All data will be entered twice by two different people for verification and identification/solution of problem fields.

To protect the confidentiality of information for the patient, all data should be stored in dedicated stand-alone computers with firewall protection and personal identifier data will be held confidentially. The link between identifiers and the data will be held password-secured and only the principal investigators and staff members designated by the principal investigators will have access to it. All hard copies of the data forms will be securely stored in Da Qing general hospital and China-Japan Friendship Hospital. Management and analysis of these data will occur under the oversight of the study steering committee.

Data management software applications will be developed for data collection and entry. To reduce the opportunity for collection and entry error, these applications will be configured to be user-friendly and transparent to those collecting and entering the data. Edit and logic checks will be conducted automatically, as invalid or out-of-range entries will be rejected.

Rigorous quality control will be implemented to ensure standardization. For data collection and entry, standardized forms will be used and a detailed manual of operations will be made available. All relevant personnel will be trained, and the data managers will bear operational responsibility for ensuring data quality.

After the completion of the study, data will be stored in a secured and stand-alone computer in China-Japan Friendship Hospital. To fully use the valuable data collected in the study, ancillary studies can be proposed by any investigator of the study group. No data can be released to researchers or identity outside the study group with personal identifiers. Using data collected in the study for research purpose should be bounded by what the study participant agreed in the consent form.

In order to ensure reliable, consistent, and unbiased collection of data, field investigators will be trained and certified in the protocol, data collection, and data processing procedures. An intensive 4-5 day workshop will be held to train personnel in all aspects of data collection, including informed consent procedures, questionnaires and interviewing procedures, physical exams, phlebotomy and laboratory procedures, data coding and data entry. Training will be conducted by persons experienced in clinical and epidemiologic measurement approaches and will be coordinated by the study Operations committee. A manual of operations for all study procedures will be used as the framework for training.

The following lab measurements will be carried out: serum creatinine, total cholesterol, triglycerides, HDL, LDL, free fatty acid, fasting glucose value, C-reactive protein, 2-hour oral glucose value (for person without diabetes), HbA1c value (all living participants).

Plasma glucose, lipids, blood urea nitrogen, and serum creatinine will be measured in Da Qing hospital according to the standard guidelines. All other biochemical parameters including blood HbA1c, insulin, and urine albumin will be measured at the laboratory of in China-Japan friendship hospital. Study samples will be stored at -80 C.

Each of the study participants in the health interview and examination will receive a summary of their individual results which they may share with their health providers.

12. Data analysis

Data are managed using the SAS (SAS Institute Inc., Cary, NC, USA). The final analytical data are verified for missing, out of range, or inconsistent values. Missing data will be filled using h appropriate statistical methods. We estimated the minimum detectable differences (MDD) expressed as the hazard ratio between the control group and Intervention groups (See Table 3). We estimated MDDs instead of sample size because the sample size for this study is fixed (530 participants minus loss to follow-up).

These calculations are based on the assumption that primary analyses will compare long-term incidence of composted microvascular or macrovascular events, first CVD event between persons originally assigned to the control group and those assigned to intervention groups. Primary analyses will combine the diet, exercise, and diet plus exercise groups into a single group. Minimum detectable differences were computed using Stata 13.1 (Stata Corp LP, College Station, Texas, USA) and were based on estimated cumulative incidence of the previous 20-year observation of Da Qing Study (Note, since the risk of event are significant related to the age, these MDD estimates are likely to be conservative). For simplicity, the calculation will be also based on the assumption that the 530 study subjects would have been individually randomized in the original trial under a 3:1 ratio (treatment vs. control). The other specific assumptions underlying the calculations of minimum detectable differences were the following:

1. Power (or 1-β) of 80%. This is the probability that if the two populations differ, the two samples will show a statistically significant result.
2. $\alpha = 0.05$; (i.e. probability of rejecting the null hypothesis when the null hypothesis is true.)
3. The underlying rates among the overall sample (i.e., all groups combined), informed by the two previous 20-year follow-up studies (Table 3).

Available sample size is 133 among control group and 397 among intervention groups, and follow-up will achieve 80% power. (Note, computations based on 90% follow-up have negligible effects on MDDs).

Table 3. Summary of minimum detectable differences (MDD) calculations

Outcome	Assumed annual risk of event among overall Population (r), %	Overall risk of event during the 30 years follow-up	Minimum detectable hazard ratio among intervention vs control
Life year (Mortality)	4.0	0.71	0.71
CVD Events*	3.2	0.62	0.70
Microvascular event	2.1	0.47	0.66

*CHD or stroke (does not include CHF, hospitalization, revascularization, etc.)

Since the study is a cluster randomized clinical trial, we will use multilevel models (e.g. SAS PROC MIXED or PROC GLIMMIX) to analyze data. In multilevel models, clusters are specified as a "random effect." The primary outcome analysis will use an overall significance level of $\alpha = 0.05$ for the confirmed development of diabetes and death. Mortality prior to the development of diabetes may be a competing risk event for the primary outcome.

The analysis will also compare the intervention groups vs. the former control group on Da Qing diabetes prevention study baseline characteristics, and any factors on which they differ will be considered for inclusion as covariates in the analysis. The analysis of the composite micro-angiopathic and cardiovascular disease outcomes will be performed in an intent-to-treat fashion as randomized, including participants who have converted to diabetes. Secondary objectives of the study are to evaluate the long-term effects of interventions on selected individual health outcomes.

A**ppendix 1.**

Study timetable

Activities	**2015**			**2016**												**2017**							
	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A
Protocol and MOP development	x	x	x																				
Assemble staff, facilities, materials				X	X	X	X																
Conduct training								X	X														
Recruitment, Clinic Visits										X	X	X	X	X	X	X	X						
Medical record review													X	X	X	X	X						
Data entry and management													X	X	X	X	X						
Data analysis																		X	X	X	X		
Presentation/ Dissemination																						X	X

Appendix 2: Human subjects

The living participants will be asked to participate in a health examination and a face-to-face interview. The health risk involved in the health examination is minimal although there are some discomforts associated with blood drawing and fasting. All necessary measures will be taken to reduce these discomforts and to ensure data confidentiality. In addition, written consent will be obtained from the participants prior to conducting physical examination and interviews. The written consent form is presented in the later section of this protocol. Formal informed consent will be obtained from study subjects following the investigational review board procedures utilized by the China-Japan Hospital in China

It is anticipated that the majority of the study participants will be contacted by either mail or telephone. Prior to any telephone or face-to-face contact, the participants will be informed about the study by letter. A written consent form will be mailed to those who have agreed to participate to sign. Thus, written consent will be obtained from all study participants before the health examination and personal interview start.

A family proxy interview is needed for the diseased study participants of the original Da Qing Study if their status of diabetes or the selected diabetes complications cannot be determined from other data sources. In this case, a face-to-face interview will be conducted. There is no direct health risk for the survey. Some family members may experience some discomfort when they talk about the death about their family members. Written consent will be obtained from the proxy prior to conducting the interview in the same way as to the living participants.

No informed consent will be solicited to review death certificates and hospital records of deceased individuals as this is considered public information.

The study provides each of the alive participants a one-on-one counseling opportunity with a health professional on how to improve her/his personal health by changing the lifestyles. She or he will receive a summary report that you can share with your health care provider.

Knowledge gained from this study will benefit the people worldwide in particular people in China and the United States by learning more about the long-term health benefits of using lifestyle intervention for preventing type 2 diabetes. Such knowledge is essential for the design and implementation of diabetes prevention strategies to reverse the trend of diabetes epidemic, which is occurring in China, the United States, as well as other parts of the world.

Appendix 3: Informed consent from for the living participants

The consent form will include the following text.

PURPOSE AND BACKGROUND

The thirty-year follow-up of the Da Qing Diabetes Prevention Study is an extension of the 20-year follow-up of Da Qing Diabetes Prevention Study, of which you were a participant. The purpose of the research project is to look at the effects of the study interventions on the development of type 2 diabetes as well as diabetes related health problems over a long period of time (up to 30 years).

Diabetes is a disease in which there is too much glucose (sugar) in the blood. Diabetes causes damage to blood vessels, heart, kidneys, eyes, and nerves. The results of the Da Qing Diabetes Prevention Study showed that the risk of type 2 diabetes was reduced by 30-50 % by changing in lifestyles (diet, exercise or both).

The thirty-year follow-up of the Da Qing Diabetes Prevention Study will examine the continued effects of these study interventions on diabetes related complications including coronary heart disease, stroke, retinopathy, nephropathy, neuropathy, and lifestyle changes over a long period of time. All participants who were in the 20-year follow-up of Da Qing Diabetes Prevention Study (approximately 393) are being asked to take part in this study.

PROCEDURES

If you choose to take part in the thirty-year follow-up of the Da Qing Diabetes Prevention Study, you will be asked to attend a clinic visit, which would take approximately 3 hours. During the visit, you will be asked general questions about your health and do the following:

1. You will be asked not to eat or drink anything except water for 12 hours before the day of your visit.
2. An electrocardiogram (ECG) will be performed. This will take about one-half hour.
3. Blood pressure will be measured in your arm. You will have the circulation in your legs checked by measuring your blood pressure in your arms and legs with a Doppler . This is a painless test.
4. Body measurements: Your height, weight and waist size will be measured.
5. You will receive a test for neuropathy (problems with nerves in the feet). This will involve an examination of the sensation in your feet and testing of your reflexes.
6. Oral glucose test: This test will take about 2 hours. You will be asked to not eat or drink anything, except water, for 12 hours before your appointment. A blood sample will be taken from your arm. You will then be asked to drink a glassful of flavored sugar water over 5 minutes. Another blood sample will be taken from your arm at 60 and again at 120 minutes. The total amount of blood drawn for this test is approximately 1 tablespoon.
7. People with diabetes will not be asked to complete the oral glucose test, but will have a fasting blood glucose drawn (approximately one tablespoon) following the same 12 hour fasting instructions as stated above. A repeat fasting blood glucose may be necessary for some persons.
8. Additional blood samples will be taken from your arm at the same time that you are having blood drawn for the oral glucose test, for lipids (blood fats), hemoglobin A1C (measure of the average blood glucose level control over 3 months) serum creatinine (a measure of kidney function), and other blood tests related to diabetes and heart disease.
9. You will be asked to provide a urine sample for the measurement of urine albumin
10. You will be asked to complete several questionnaires. You may be asked questions about your health, medications, physical activity, diet and feelings.

11. We have previously asked you to give us personal information such as address, phone numbers, to help us to reach you if we lose touch.
12. You may be asked to have an evaluation of the back of your eyes using retinal photography. You will have pictures taken with a camera of the back or your eyes (retina).

These tests and surveys are similar to those you had when you have had previously when you were taking part in the 20-year follow-up.

RISKS AND DISCOMFORT

Oral Glucose Tolerance and Blood Tests: The risks of drawing blood include temporary discomfort from the needle stick, possible bruising or redness of the skin, lightheadedness, and on rare occasion, infection. It is possible that some may get nausea or an upset stomach with the glucose (sugar) drink that is given during the oral glucose test. Rarely some people may experience a mild low blood sugar reaction (symptoms like nervousness or sweating) at the end of the test. You will be given a snack to guard against this.

Electrocardiogram (ECG): The risks associated with the use of the ECG electrodes include possible skin irritation, redness and/or chaffing at the application site.

Retinal photography: No drops will be needed to be put in eyes to dilate your pupils. Photographs do not injury your eyes in any way.

BENEFITS
The study provides you a one-on-one counseling opportunity with a health professional on how to improve your personal health by changing your lifestyles. You will receive a summary report that you can share with your health care provider. Your participation in this study may benefit society by learning more about the complications that may happen in persons with type 2 diabetes and the relationships between blood sugar levels and complications.

Finally, you should understand that the information that we receive from you will be kept confidential.

OTHER INFORMATION

Participation in this study is completely voluntary. You are free to take back your consent and stop taking part in this study at any time. You are also free to refuse to answer any questions. You may ask any questions about the study at any time. Your current or future care will not be affected by your stopping the study. If you have any questions about your rights as a research subject, you can call Dr.XXX (name of the contact person) at XXXXX (phone number of the contact person).

COSTS AND PAYMENTS: All examinations will be free of charge. You will receive 50 Yuan for transportation expenses to the examination.

PARTICIPANT'S STATEMENT:
The study described above has been explained to me. I understand that I am consenting to participate in the long term follow-up of the Da Qing Diabetes Prevention Study. If I have any questions, I know that I can contact one of the investigators.

_____

Participant Printed Name

_____

Participant's Signature Time Date

_____

Investigator Signature Date

Appendix 4. Informed consent from for the proxy interview

The consent form will include the following text.

PURPOSE AND BACKGROUND

The thirty-year follow-up of the Da Qing Diabetes Prevention study is an extension of the 20-year follow-up of Da Qing Diabetes Prevention Study, of which your_____ was a participant. The purpose of the research project is to look at the effects of the study interventions on the development of type 2 diabetes as well as diabetes related health problems over a long period of time (up to 30 years).

Diabetes is a disease in which there is too much glucose (sugar) in the blood. Diabetes causes damage to blood vessels, heart, kidneys, eyes, and nerves. The results of the Da Qing Diabetes Prevention Study showed that the risk of type 2 diabetes was reduced by 30-50 % by changing in lifestyles (diet, exercise or both).

The thirty-year follow-up of the Da Qing Diabetes Prevention Study will examine the continued effects of these study interventions on overall and cause-specific mortality, and diabetes related complications including coronary heart disease, stroke, blindness, and amputation over a long period of time. For those who are deceased, we need to know the date, place and cause of their deaths as well as their status of diabetes and diabetes-related complications. We like to conduct a short personal interview to see if you can provide such information.

INTERVIEW QUESTIONS

The interview questionnaire has 19 questions, which are related to the time, place, and cause of death, as well as the status of diabetes and diabetes-related complications. The interview will take approximate 20 minutes of your time. The information you provide will be completely confidential and restricted to the research purpose only.

RISKS AND DISCOMFORT
There is no direct health risk for the survey. Some family members may experience some discomfort when they talked about the death about their family members.

BENEFITS
There is no direct benefit by participating in this survey. Your participation in this study may benefit society by learning more about the complications that may happen in persons with type 2 diabetes and the relationships between blood sugar levels and complications.

Finally, you should understand that the information that we receive from you will be kept confidential.
OTHER INFORMATION
Participation in this study is completely voluntary. You are free to take back your consent and stop taking part in this study at any time. You are also free to refuse to answer any questions. You may ask any questions about the study at any time. If you have any questions about your rights as a research subject, you can call Dr.XXX (name of the contact person) at XXXXX (phone number of the contact person)

COSTS AND PAYMENTS: You will receive 50 Yuan for transportation expenses to the place where the interview will be conducted.

PARTICIPANT'S STATEMENT:
The study described above has been explained to me. I understand that I am consenting to participate in the survey. If I have any questions, I know that I can contact one of the investigators.

_____
Participant Printed Name

_____
Participant's Signature Time Date

_____
Investigator Signature Date
_____

Appendix 5.

I. Proxy survey questionnaire
II. Medical record review form,
III. Hospitalization form,
IV. Patient interview questionnaire

代理人问卷
PROXY SURVEY

一、患者情况 Characteristics of the patient

患者姓名: Name of the patient

86 年编号: ID in year 1986

受试者身份证号: Personal Identification Number (equal to U.S. SSN) of the patient

患者出生日期: Date of birth of the patient

患者性别: Sex of the patient 1☐男 Male 2☐女 Female

代理人姓名: Name of the proxy

家庭住址: Address

家庭电话: Home phone number

手机: Cell phone number

随访日期: Date of interview

记录者签名: Signature of the interviewer

1. 你与受试者的关系?

What is your relationship with the patient?

1☐配偶 Spouse 2☐子女 Children 3☐朋友 Friends 4☐邻居 Neighbor

5☐ 其他 Other _____

2. 有死亡证明书吗？

Do you have his/her death certificate?

1☐是 Yes *（如有，请复印 If yes, please make a copy）*
2☐否 No

3. 死亡日期?

When did he/she die?

日期 Date (月/ 年 month/year): ___ ___/___ ___ ___ ___

4. 死亡地点?

Where did he/she die?

1☐医院 name of the Hospital 2☐家中 Home 3☐其他地方 Other _____ 8☐不详 Unknown

5. 直接死亡原因?

What is the major cause of his/her death? _____

5a. 导致死因的疾病

Which disease was directly associated with this major cause of death?

1☐ 高血压 High Blood Pressure 2☐ 高血脂 Hypercholesterolaemia

3☐其他心血管疾病 Other Cardiovascular diseases
4☐糖尿病 Diabetes
5☐肾病 Kidney diseases 6☐截肢 Amputation 7☐深静脉血栓 Deep vein thrombosis
9☐其他 Other（包括感染 infection 、肿瘤 tumor 外伤 trauma、中毒 poison 、肺心病 pulmonary heart disease、电解质紊乱 Electrolyte Disorders 等）

二、患者生前的病史
Medical history of the patient (before his/her death)

6. 你的_____一般在什么地方看病?

Which hospital/clinic did the patient usually go to?

诊所: Clinic

a) 名称 name_____
地址 address_____

b) 名称 name_____
地址 address_____

c) 名称 name_____
地址 address_____

医院: Hospital

d) 名称 name_____
地址 address_____

e) 名称 name_____
地址 address_____

f) 名称 name_____
地址 address_____

注: 下列问题是 1992 年大庆糖尿病干预研究至去世前关于你的_____的健康情况。

The following questions are related to the 1992 Da Qing diabetes prevention and intervention study. The questions are correlated to the patient's health conditions before his/her death.

7. 你的_____是否吸烟

Has he/she ever smoked?

0☐否 No 1☐是 Yes 8☐不详 Unknown

开始时间 Starting Date (月 / 年 Month/Year): _____/_____

8. 你的_____死亡之前是否有医生告诉他或她有糖尿病?

Before his/her death, has he/she ever been told by the doctor that he/she had diabetes?

0☐否 No ***(如果否, 跳到问题 17 If no, go to question 17)***

1☐是 Yes 8☐不详 Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

8a. 如果他或她有糖尿病, 是否使用胰岛素?

If he/she had diabetes, was insulin used?

0☐否 No 1☐是 Yes 8☐不详Unknown

9. 是否有医生告诉你的_____有中风

Has he/she ever been told by the doctor that he/she had stroke?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

10.是否有医生告诉你的_____有心梗?

Has he/she ever been told by the doctor that he/she had heart attack (Myocardial Infarction)?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

11. 是否做过心脏搭桥手术?

Has he/she ever had heart bypass surgery?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

12. 是否做过心脏支架手术?

Has he/she ever had heart stent surgery?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

13. 是否做过颈部和脑部的手术?

Has he/she ever had cervical or brain surgery?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

14. 是否做过透析?

Has he/she ever had dialysis?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

15. 是否做过肾移植?

Has he/she ever had kidney transplantation?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

16. 是否做过眼底激光手术?

Has he/she ever had fundus laser surgery?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

17. 是否有失明?

Was he/she ever blind?

0☐否 No 1☐是 Yes 8☐不详Unknown

17a. 标明单双侧

Was it one side or both sides?

1☐单侧 One side 2☐双侧 Both sides

如果是, 何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

18. 是否有持续1个月以上难以愈合的足部溃疡?

Has he/she ever had ulcer on his/her feet that took more than one month to heal?

$_{0}$☐否 No $_{1}$☐是 Yes $_{8}$☐不详Unknown

如果是，何时开始? If yes, starting when

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

19. 是否有足趾/足部/腿部截肢 (排除外伤、车祸、肿瘤)?

医疗文件查阅资料
MEDICAL CHART REVIEW

患者姓名: Name of the patient

86 年编号: : ID in year 1986

受试者身份证号: Personal Identification Number (equal to U.S. SSN) of the patient

患者出生日期: Date of birth of the patient

患者性别: Sex of the patient 1☐男 Male 2☐女 Female

家庭住址: Address

配偶姓名: Name of the spouse

家庭电话: Home phone number

子女姓名: Name of children

子女住址: Address of children

子女电话: Phone number of children

随访开始日期 Starting date of follow-up interview :1986 年 Year____ 月 Month

随访结束日期: Ending date of follow-up interview

记录完成日期: Date of record

记录者签名: Signature of the recorder

资料来源 Data Source

住院部名称: Name of the hospital _____

住院部地址: Address of the hospital _____

患者病史 Medical History of the Patient

1. 病历是否记录患有糖尿病

Has diabetes ever been recorded in the participant's medical record?

0☐否 No 1☐是 Yes 8☐不详Unknown

1a. 如果是, 记录首次出现糖尿病的年月

If yes, when was the first time it was recorded?

.(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

1b. 病历是否记录空腹血糖 >=126mg/dl 或 7.0mmol/L?

Has fasting blood glucose >=126mg/dl or 7.0mmol/L ever been recorded?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 记录首次出现的年月.

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

如果是,记录数值 If yes, please record the number _____

1c. 病历是否记录空腹血糖 >=140mg/dl 或 7.8mmol/L?

Has fasting blood glucose >=140mg/dl or 7.8mmol/L ever been recorded?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 记录首次出现的年月.

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

如果是,记录数值 If yes, please record the number _____

1d. 病历是否记录 2 小时血糖 >=200mg/dl 或 11.1mmol/L?

Has 2-hour blood glucose >=200mg/dl or 11.1mmol/L ever been recorded?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 记录首次出现的年月 If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

如果是,记录数值 If yes, please record the number _____

2.心血管危险因素病史(回答全部项目)

Risk factors of cardiovascular diseases

2a. 高血压(HTN) Hypertension

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 记录首次出现高血压的年月.

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

数值 If yes, please record the number ：_____

2b. 高酯血症/高胆固醇血症

Hyperlipidemia / Hypercholesterolemia
0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录首次出现高酯血症/高胆固醇血症的年月 If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

数值 If yes, please record the number ：_____

2c. 吸烟史 Smoking history
0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录开始吸烟 的年月
If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

如果已戒烟 ，记录戒烟的年月

If the patient stopped smoking, when was the time he stopped?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

3.中风史 Stroke history

3a. 是否发生过中风?
0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录首次发作的年月
If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

随访期间发作次数 How many times?：共_____ 次
第_____ 次 First time： 记录中风种类 Type of stroke：可能是 1☐出血 Hemorrhage 2☐缺血 Ischemia 3☐原因不明 Unknown
第_____ 次 Second time： 记录中风种类 Type of stroke：可能是 1☐出血 Hemorrhage 2☐缺血 Ischemia 3☐原因不明 Unknown
第_____ 次 Third time： 记录中风种类 Type of stroke：可能是 1☐出血 Hemorrhage 2☐缺血 Ischemia 3☐原因不明 Unknown
第_____ 次 Fourth time： 记录中风种类 Type of stroke：可能是 1☐出血 Hemorrhage 2☐缺血 Ischemia 3☐原因不明 Unknown

4.心脏病史 Heart disease history

4a. 是否有心绞痛的任何证据

Has there ever been evidence of Angina?
0☐否 No 1☐是 Yes 8☐不详Unknown

记录首次发作的年月

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

4b. 需要住院的不稳定性心绞痛

Has he/she ever had an unstable Angina that needs hospital stay?
0☐否 No 1☐是 Yes 8☐不详Unknown

记录首次发作的年月

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

4c. 是否有心肌梗死(MI)
Has he/she ever had Myocardial Infarction?
0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录首次发作的年月
If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___
随访期间心肌梗死发作次数 How many times? :_____
是否有心电图记录 Has there ever been records of ECG?
0☐否 No 1☐是 Yes 8☐不详Unknown

4d. 是否发生需要住院的充血性心衰

Has he/she ever had congestive heart failure that needs hospital stay?
0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录首次发作的年月
If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

4e. 有无明显的其他冠心病的证据（定义：冠脉造影显示狭窄 50%）

Has he/she ever had evidence of other coronary heart disease? (Definition: Coronary angiography showed narrow and limited > 50%)
0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录首次发生的年月

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

4f. 是否发生需要住院的心律失常的证据

Has he/she ever had evidence of Arrhythmia that needs hospital stay?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录首次发作的年月

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

5. 周围血管闭塞性疾病（PVOD）/间歇性跛行

Has he/she ever had peripheral vascular occlusive disease/ intermittent claudication?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录首次发作的年月

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

6. 血管疾病治疗情况:

Vascular disease and treatment

6a. 颈动脉内膜切除术

Carotid endarterectomy

0☐否 No 1☐是 Yes 8☐不详Unknown

- 手术次数 How many times?: _____

记录首次手术的年月 If yes, when was the first time it was recorded?

: ___ ___/___ ___ ___ ___

6b. 冠状动脉成形术 Coronary Angioplasty

0☐否 No 1☐是 Yes 8☐不详Unknown

- 手术次数 How many times?: _____

记录首次手术的年月 If yes, when was the first time it was recorded?

: ___ ___/___ ___ ___ ___

6c. 冠状动脉搭桥术 (CABG)

Coronary bypass surgery (coronary artery bypass graft)

0☐否 No 1☐是 Yes 8☐不详Unknown

- 手术次数 How many times?: _____

记录首次手术的年月 If yes, when was the first time it was recorded?

: ___ ___/___ ___ ___ ___

6d. 周围血管成形术或搭桥术

Peripheral angioplasty or bypass surgery

0☐否 No 1☐是 Yes 8☐不详Unknown

- 手术次数 How many times?: _____

记录首次手术的年月 If yes, when was the first time it was recorded?

: ___ ___/___ ___ ___ ___

7. 肾脏疾病治疗情况

Kidney diseases and treatment

7a.是否有记录显示有无终末期肾病

Has there ever been a record of end stage renal disease?

0☐否 No 1☐是 Yes 8☐不详Unknown

记录首次血肌酐>2mg/dl 或 176umol/L 的年月 If yes, when was the first time Scr >2mg/dl or 176umol/L?

: ___ ___/___ ___ ___ ___

7b. 透析 Dialysis

0☐否 No 1☐是 Yes 8☐不详Unknown

肾透析次数 How many times?: _____

记录首次手术的年月 If yes, when was the first time it was recorded?

: ___ ___/___ ___

7c. 肾移植 Kidney transplantation

0☐否 No 1☐是 Yes 8☐不详Unknown

肾移植次数 How many times?: _____

记录首次手术的年月 If yes, when was the first time it was recorded?

: ___ ___/___ ___

8. 糖尿病视网膜病变 Diabetic retinopathy

8a. 是否有记录显示有视网膜病变

Has there ever been a record of diabetic retinopathy?

0☐否 No 1☐是 Yes 8☐不详Unknown

8b. 是否记录做过眼底激光治疗

Has there ever been a record of fundus laser treatment?

0☐否 No 1☐是 Yes 8☐不详Unknown

如果是, 记录激光的年月及原因

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

原因 Reason _____

8c. 失明 Blindness
0☐否 No 1☐是 Yes 8☐不详Unknown

标明单眼或双眼

1☐单侧 One side 2☐双侧 Both sides
如果是，记录失明的年月及原因

If yes, when was the first time it was recorded?

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

原因 Reason _____

9. 足/足趾/腿截肢 (排除车祸、外伤、肿瘤)

Amputation of toe, foot, or part of a leg (excluding trauma, auto accident, and tumor)
0☐否 No 1☐是 Yes 8☐不详Unknown

如果是，记录截肢的年月 If yes, when was the first time it was recorded?

:

(月 / 年 Month/Year): ___ ___/___ ___ ___ ___

2006 年以后住院记录 Hospitalizations Since 2006

就诊日期（年/月/日） Date (Year/Month/Day)	就诊原因 Major Complaint	住院天数 Days of Hospitalization	总花费 Total Costs

大庆随访研究患者随访咨询
Patient Survey Questionnaire

请参见大庆随访表填写指南

随访日期:	___ ___/___ ___/___ ___ (月) (日) (年)
记录者编号:	_____ _____ _____ _____ _____

患者情况	
1. 患者编号	
2. 患者姓名	
3. 患者出生日期:	____ ____/____ ____/____ ____ ____ ____ (月) (日) (年四位)
4. 患者性别:	男 1☐ 女 2☐

糖尿病情况

5. 是否有医生告诉你有糖尿病或高血糖?

0☐ 否 ***(回答问题 10)***

1☐ 是

8☐ 不知道

6. 第一次被告知患有糖尿病时你年龄多大?

____ *岁* ***(回答问题 7)***

8☐ 不知道

6a. 你是否记得哪一年被诊为糖尿病?

(*月 / 年*): ___ ___/___ ___ ___ ___ ***(回答问题 7)***

8☐ 不知道

7. 你正在用胰岛素吗?

0☐ 否
1☐ 是

8. 你用胰岛素多久了?

_____*月*

9. 你正在用口服降糖药吗?

0☐ 否
1☐ 是
8☐ 不知道

患者生活方式

10. 到目前为止，你吸烟超过100支吗?

0☐ 否 ***(如果否，回答问题 12)***
1☐ 是
8☐ 不知道

11. 你年龄多大时开始经常吸烟?

_____ 岁

8☐ 不知道

12. 过去的1年，你吸烟吗?

1☐ 否 ***(如果否，回答问题 15)***
2☐ 有时
3☐ 每天
8☐ 不知道

13. 若吸烟，平均每天吸多少支烟?

1☐ 15-20
2☐ 10-14
3☐ 5-9
4☐ 不足 5

14. *如果已戒烟，何时戒烟的*?

(*月 / 年*): ___ ___/___ ___ ___ ___

15. 你喝含酒精的饮料吗？（问：你喝白酒吗？）

1☐ 从不 ***(如果从不，回答问题 17)***
2☐ 大约每月
3☐ 1 月 2-数次
4☐ 1 周 2-3 次

5☐ 1 周 4-数次

8☐ 不知道

16. 你饮酒时，一般喝几杯含酒精的酒? （问：你喝几杯白酒？）

1☐ 1 或 2

2☐ 3 或 4

3☐ 5 或 6

4☐ 7 或 9

5☐ 10 杯以上

8☐ 不知道

注:下面的问题是关于过去 1 周体力活动所花时间.请回答每个问题，即使你不是一位喜欢运动的人。想一想工作和家中所有的活动以及空闲时间的锻炼和运动。

注: 想一想过去 1 周你做过的所有剧烈的活动。剧烈的活动会令你呼吸比平常更急促,包括举重物，种地，需氧运动和,快速骑车。只考虑持续每次至少 10 分钟的活动。

17. 过去1周，你有几天做强烈的体力活动? _____ _____ 每周几天

18. 你当时每天有几小时强烈的体力活动?

__ __ 小时/每天 或 _ 分钟/每天

注: 想一想过去 1 周你做过的所有中度的活动所花时间。中度活动会令你呼吸比平常急促些,，包括提物，正常速度骑车和打网球，不包括散步。只考虑持续每次至少 10 分钟的活动 。

19. 过去1周,你有多少天做中度的体力活动??

____ 天/每周

20. 当时 你做几小时中度的体力活动?

__ __小时 /每天 或 __ __ _分钟/每天

注: 想一想过去 1 周你步行所花时间. 这包括工作和家中行走以及运动和休闲的步行运动

21. 过去1周，有多少天你至少步行1次10分钟?

____天/每周

22. 当时 你一天步行几小时?

__ __ 小时/每天 或 __ __ _多少分钟/_每天

注: 想一想过去 1 周你坐着所花时间. 这包括工作和家中坐在桌前以及访友,读书,作着或躺着看电视

23. 过去1周,你在工作日,有多少时间坐着工作?

__ __ 几小时/工作日 或__ __ __分钟/工作日

患者健康情况

24. 总体来说,你认为你自己健康状况如何:

1☐ 非常好
2☐ 很好
3☐ 好
4☐ 一般
5☐ 不好

注:下面 5 个问题是关于你认为你的健康如何,选择贴切的答案.

25. 你的运动能力如何:

1☐ 我行走没问题
2☐ 我行走有点儿问题
3☐ 我卧床不起

26. 你生活的自理能力如何?:

1☐ 我自理没问题
2☐ 我洗漱和穿衣有点儿问题
3☐ 我不能自己洗漱和穿衣

27. 你的日常活动如何 (如你的工作,学习,家务和休闲活动):

1☐ 我日常活动没问题
2☐ 我日常活动有点儿问题
3☐ 我不能自己从事日常活动

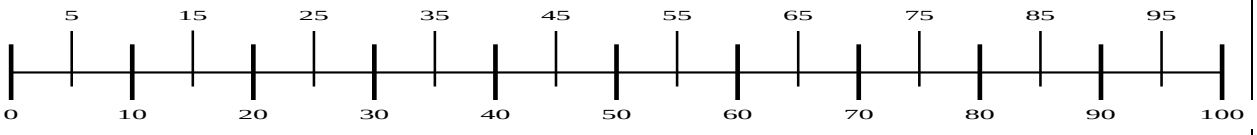
28. 疼痛和不适:

1☐ 我没有疼痛和不适
2☐ 我有些轻微疼痛和不适
3☐ 我有严重的疼痛和不适

29. 焦虑和抑郁。今天如何:

1☐ 我没有焦虑和抑郁
2☐ 我有些焦虑和抑郁
3☐ 我特别焦虑和抑郁

30. 为了帮助您判定自我健康状态的好坏，我们画了下面的范围.假定最好是100分，最坏是0分。请用圆圈标出你今天的健康状态所在位置。



我们不能确定原来研究期间收集的 3 天日食物消耗是否必要。请提出你的看法。

3 天日食物消耗

	第一天	第二天	第三天
	日期（日/月/年）	日期（日/月/年）	日期（日/月/年）
早餐			
数量（g）			
中餐			
数量（g）			
晚餐			
数量（g）			
加餐			
数量（g）			
食用油			
数量（g）			
食用糖			
数量（g）			
液体			
数量（g）			
其它			

填表指导：请记录准确的主食种类：米、面、玉米面等；副食种类：猪肉、牛肉、羊肉、内脏，记录数量、肥瘦；鱼，准确的种类和数量；蛋的种类和数量；牛奶，鲜奶还是奶粉；蔬菜。加餐指除三餐外的食物，包括瓜子、花生、水果、糖果、点心等；食用油的种类和数量；食用糖，不包括糖果，主要指烹饪用糖和淀粉；酒精摄入的种类和数量。以上不包括假日和采血日的情况。

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