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Study design, recruitment, and baseline characteristics: the Department of Veterans Affairs Dental Diabetes Study

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Abstract

Objectives: We are conducting a clinical trial of the efficacy of periodontal therapy in the improvement of glycaemic control in veterans with poorly controlled diabetes. This report describes study design, recruitment and randomization and compares baseline characteristics of the sample frame with those randomized into study groups.

Methods: Veterans with poorly controlled diabetes were randomized in two groups: immediate periodontal therapy (''early treatment'') or usual care followed by periodontal therapy (''deferred treatment''). Half of each group continued care for 12 months; the other half returned to their usual care. We studied baseline patient characteristics, self-reported health measures, and clinical examination data. We examined means for continuous variables, frequencies for categorical variables and compared groups using *t*-tests and χ^2 tests ($\alpha = 0.05$ for both).

Results: The 193 randomized participants were younger (58 years) and had slightly higher HbA1c (10.2%) than the 2534 non-randomized participants (64 years, HbA1c = 9.8%). The deferred treatment group was more likely than the early treatment group to have a history of stroke, transient ischaemic attacks, and less likely to be current or former smokers.

Conclusions: The mechanism for randomization was largely successful in this study.

Key words: clinical trial; design; diabetes; glycaemic control; HbA1c; periodontal disease; recruitment

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Data on the efficacy of periodontal care on improving glycaemic control in poorly controlled diabetes are equivocal (Taylor 1999, 2001, 2003, US Department of Health and Human & Services. 2000). A two-way relationship between diabetes and periodontitis has been postulated (Grossi & Genco 1998; Iacopino 2001), but supporting data are sparse. Several studies suggest that improvements in periodontal condition will improve glycaemic control (Miller et al. 1992, Taylor et al. 1996, Grossi et al. 1997; Iwamoto et al. 2001, Stewart et al. 2001), while others suggest that this is not the case (Seppala & Ainamo 1994, Aldridge et al. 1995, Smith et al. 1996, Westfelt et al. 1996, Firatli 1997, Christgau et al. 1998, Collin et al. 1998). Taylor (2001, 2003) and Stewart et al. (2001) recommend controlled clinical trials to address this issue. We are conducting a multi-site, single-blind, randomized clinical trial to determine the efficacy of periodontal care in the improvement of glycaemic control in veterans with poorly controlled diabetes at four Department of Veterans Affairs facilities in New England. This paper describes the study design, recruitment and baseline characteristics in this clinical trial.

Methods

The institutional review boards at each of the facilities approved the study. Each participant gave informed consent.

Design

This clinical trial has a two-by-two design (Fig. 1). In one direction, the analyses will examine whether periodontal therapy (scaling, root planing, doxycycline 100 mg by mouth once daily for 14 days and twice daily rinsing with 0.12% chlorhexidine rinse) improves glycaemic control over a 4-month period. Veterans with diabetes

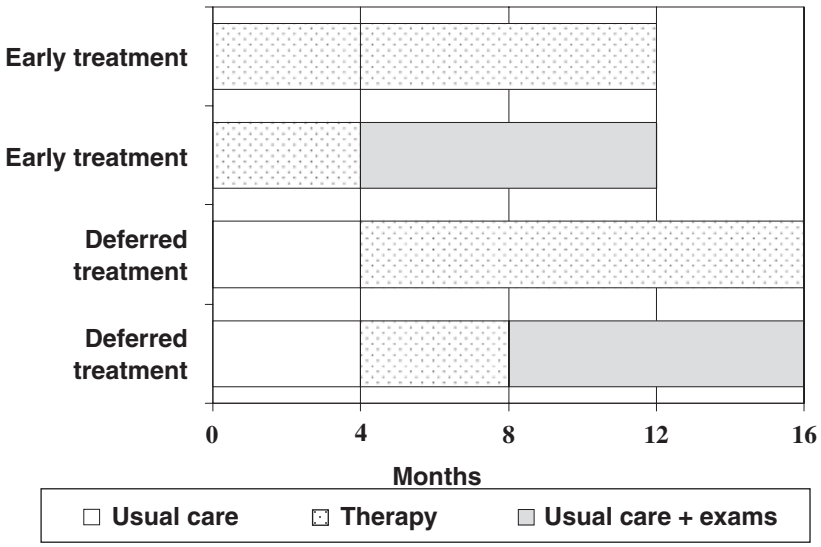

Fig. 1. Study design: VA Dental Diabetes Study.

were initially randomized to deferred treatment (their usual medical and dental care) or an early treatment group. Patients initially randomized to deferred treatment received the same examination and treatment after 4 months. After the initial therapy, half of each group was randomized to return to their usual providers of care and the other half to continued periodontal therapy for an additional 8 months (12 months of total therapy).

Identification and recruitment

We identified veterans with one or more HbA1c values $\geq$ 8.5% within the last 6 months and contacted their primary care providers to obtain their concurrence to contact their patients. Because all participants were veterans whose admission to military service was on the basis of their health, and thus developed diabetes after the beginning of military service, we reasoned that the vast majority of them had Type 2 diabetes. We then sent a letter to the veteran describing the study in general terms and inviting them to participate. Veterans could indicate their interest (yes/no) using a preaddressed postage-paid postcard. The letter informed potential participants that they would be contacted in 2 weeks if the postcard was not returned with an indication of ''no'' interest. After 2 weeks, veterans were called to determine interest and eligibility (willing and sufficiently healthy to participate in a 12–16-month study, and $\geq$ 8 teeth) using a standardized script. Interested veterans were asked to return for a blood test to confirm poor glycaemic control.

Inclusion/exclusion criteria

Inclusion criteria included a repeat HbA1c of 8.5% or above, a minimum of eight natural teeth, periodontal treatment need as evidenced by the Community Periodontal Index of Treatment Need CPITN (Ainamo et al. 1982) scores of three or four in at least two sextants on examination, and sufficient health and willingness to complete the 12–16- month study.

Exclusion criteria included grave medical or psychiatric illness or severe immune compromise (e.g. HIV or cancer).

Randomization

Eligible and interested veterans were randomized into four study groups using a stratified schema (Fig. 1):

1. *Early treatment/4 months therapy:* early treatment for four months [periodontal scaling and root planing plus doxycycline (100 mgm q.d. for 14 days), and chlorhexidine rinses (0.12% twice daily for 4 months)], and then usual care (usual medical and dental care);
2. *early treatment/12 months therapy:* early treatment, continued for 12 months;
3. *deferred treatment/4 months therapy:* usual care, 4 months of treatment, and then usual care (usual medical and dental care); and
4. *deferred treatment/12 months therapy:* usual care and then 12 months of treatment.

We stratified by site (Boston *versus* Providence *versus* (Manchester+Bedford)] because we expected differences in populations with respect to frequencies of minority and low-income veterans. We used PROC PLAN in Statistical Analysis Systems (SAS) Version 8.1, Cary, NC, USA) to obtain 12 blocks of eight, using a seed of 020348. Group assignments were put on white cards and sealed in white envelopes and numbered consecutively. Study staff took the top envelope to assign study group.

Baseline measures

We obtained data on age, HbA1c, and comorbid medical conditions from the VA Outpatient Clinic File (OPC). The OPC is comprised of three different data sets, of which we used two: the visit file with demographics and date of visit, and the diagnosis file with International Classification of Diseases, Version 9, Clinical Modification (ICD-9-CM) codes for each visit. We used data from outpatient visits for 3 years before the baseline HbA1c and listed all unique diagnoses of co-morbid medical conditions. We also obtained clinical data on number of teeth, CPITN scores (Ainamo et al. 1982), Gingival index (Löe 1967), gingival recession (in mm), pocket depth (six sites per tooth, twice), exudate on palpation and probing and self-reported (questionnaire) data on race, sex, smoking status, body mass index (BMI), duration of diabetes, oral and general health, stress, activity level, alcoholic drinks per week, diabetes medicines (insulin and oral medications), and dental visit in the last year.

Analyses

χ^2 and *t*-tests were used to test for differences ($\alpha = 0.05$) between the sample frame and the study participants, and between groups.

Results

We recruited 193 participants from our sample frame of 2727 veterans with HbA1c $\geq$ 8.5% (Fig. 2). Primary care providers consented to our contacting two-thirds (67%) of the veterans, 11% responded that the veteran was not a good candidate, and 22% did not respond after at least five attempts. Of the veterans we attempted to contact, 12% refused to participate, 14% could not be reached, 13.5% were ineligible because they had $<$8 teeth (11.6%),

Table 1. Baseline characteristics of study groups in VA Dental Diabetes Study

Variable	Randomized ($N = 193$)	Non-randomized $N = 2534$	Deferred treatment $n = 95$	Early treatment $N = 98$	4-month group $N = 98$	12-month group $N = 92$
Age	58.36‡	64.49	58.96	57.79	58.08	58.39
Pre-baseline HbA1c	10.18‡	9.79	10.29	10.07	10.12	10.26
Number of medical diagnoses in last 3 years	29.62	27.05	30.58	28.69	30.19	29.37
Co-morbidity index	6.03	5.83	6.11	5.95	6.15	5.91
Diabetes w/no complications (%)	47.7	48.3	45.3	50.0	52.0	43.5
Diabetes w/ketosis (%)	2.1	1.7	2.1	2.1	1.0	3.3
Diabetes w/nephropathy (%)	4.2	3.6	7.4*	1.0	3.1	5.4
Diabetes w/retinopathy (%)	26.4	25.6	30.5	22.4	23.5	30.4
Diabetes w/neuropathy (%)	17.7	18.3	15.8	19.4	20.4	15.2
Diabetes w/PVD (%)	4.2	6.8	4.2	4.1	4.1	4.4
Diabetes w/other complications (%)	38.9	38.7	40.0	37.8	31.6*	45.6
Hypercholesterolaemia	53.4	52.3	53.7	53.1	50.0	56.5
Hypertension (%)	67.9	69.3	68.4	67.4	70.4	65.2
Thyroid disease (%)	7.8	5.0	7.4	8.2	5.1	10.9
Depression (%)	28.0*	21.3	23.2	32.4	28.6	28.3
Schizophrenia (%)	5.2	6.0	5.3	5.1	8.1	2.2
PTSD (%)	19.2§	11.6	16.8	21.4	21.4	17.4
Anxiety (%)	14.0	12.2	16.8	11.2	13.3	15.2
Bipolar disorder (%)	10.4*	6.0	8.4	12.2	10.2	10.9
Tobacco use (%)	16.6	14.2	12.6	20.4	17.4	16.3
Alcohol use (%)	11.9	9.8	9.5	14.3	13.3	10.9
Drug use (%)	7.3*	4.2	6.3	8.2	9.2	5.4
Obesity (%)	42.0*	34.8	44.2	39.8	44.9	39.1
Stroke (%)	7.8	9.2	11.6*	4.1	6.1	7.6
TIA (%)	2.6	4.9	5.3*	0.0	3.1	2.2
COPD (%)	18.1	18.7	21.0	15.3	17.4	19.6
PVD (%)	13.0	18.3	10.5	15.3	8.2*	18.5
CAD (%)	6.7	7.3	7.4	6.1	7.1	6.5
Atherosclerosis (%)	38.3	41.0	39.0	37.8	36.7	39.1
Angina (%)	10.4	10.5	10.5	10.2	11.2	9.8
Osteoarthritis (%)	23.3	23.2	26.3	20.4	25.5	19.6
Glaucoma (%)	24.9	22.8	21.0	28.6	20.4	28.3

*$p < 0.05$.
§$p < 0.01$.
‡$p < 0.0001$.
The following ICD-9-CM codes were used in these analyses: diabetes w/no complications (250.0), diabetes w/ketosis (250.1), diabetes w/nephropathy (250.4), diabetes w/retinopathy (250.5, 362.0, 366.41), diabetes w/neuropathy (250.6, 357.2), diabetes w/PVD (250.7), diabetes w/other complications (250.2, 250.3, 250.8, 250.9), hypercholesterolaemia (272), hypertension (401, 405, 437.2, 642.9), thyroid disease (240–246), depression (296.2, 296.3, 300.4, 311), schizophrenia (295), PTSD (309.81), anxiety (300.0, 300.2, 300.3), bipolar disorder (296.0, 296.1, 296.4–296.9), tobacco use (305.1), alcohol use (303, 305.0), drug use (304, 305.2–305.9), obesity (278.0), stroke (430–432, 433.01, 433.11, 433.21, 433.31, 433.81, 433.91, 434.01, 434.11, 434.91, 436, 437.1, 438), TIA (436), COPD (491–493, 496), PVD (440, 443.8, 443.9, 785.4), CAD (410, 411.0, 411.8, 412), atherosclerosis (414), angina (411.1, 413), osteoarthritis (715) and glaucoma (365).
HbA1c, haemoglobin A1c; PTSD, post-traumatic stress disorder; TIA, transient ischaemic attack; COPD, chronic obstructive pulmonary disease; PVD, peripheral vascular disease and CAD, coronary artery disease.

died before contact (1%) or other medical reasons (0.9%), and another 10% were ineligible because their HbA1c decreased below 8.5%. This left 193 (7.1%) eligible for randomization, who were then contacted, gave consent, and were randomized.

The baseline characteristics of the study groups are shown in Table 1. Veterans randomized were younger and had higher HbA1c, and more likely to have a history of obesity, drug use, depression, bipolar disorder, or post-traumatic stress disorder (PTSD). Participants in the deferred treatment group are more likely to have a history of stroke, TIAs, and diabetes with nephropathy. Peripheral vascular disease and diabetes with other complications were more common in the groups with 12 months of therapy.

Baseline characteristics by study group for sociodemographic and general and oral health variables are shown in Table 2. There were fewer current (19%) and former (50%) smokers in the deferred treatment than the early treatment group (30% and 58%, respectively). Participants in the 4-month therapy group reported walking more blocks per day and had higher worst pocket depths than the 12-month group.

Discussion

The design in this study will allow us to determine the efficacy of periodontal therapy in improving glycaemic control over 4 and 12 months. Moreover, data presented here suggest that the randomization in this clinical trial was largely effective. Study groups are generally similar with respect to baseline characteristics, overall illness burden, severity of diabetes, dental characteristics and questionnaire data. Because we found differences in history of stroke and TIAs, and diabetes with nephropathy between the early treatment and usual

Table 2. Baseline sociodemographic, health, and dental characteristics, VA Dental Diabetes Study

Characteristic	*N*	Deferred treatment	Early treatment	*N*	4-month therapy	12-month therapy
Sex (% male)	165	94.0*	100.0	162	96.3	98.8
Race (% white)	159	78.5	83.8	156	73.8	88.2
Marital status (% married)	161	55.6	48.8	158	50.0	53.8
Smoking status (%)						
Current	158*	18.8	29.5	155	26.9	22.1
Former		50.0	57.7		50.0	55.8
Never		31.2	12.8		23.1	22.1
Baseline HbA1c	165	10.2	9.9	165	10.0	10.1
BMI (sr)	161	31.5	32.8	161	32.7	31.8
Duration of diabetes	154	14.1	11.4	154	12.0	13.2
General health (sr, reversed)	160	2.6	2.5	160	2.6	2.5
Oral health (sr, reversed)	158	2.4	2.3	158	2.5	2.5
Stress	160	5.6	4.8	160	5.3	5.1
Flights climbed/day	157	4.4	5.2	157	5.4	4.0
Blocks walked/day	156	7.8	5.7	156	8.9*	4.7
Alcoholic drinks per week	161	1.4	2.2	161	1.5	2.2
Dental visit within 1year (%)	160	59.3	49.4	157	54.4	55.1
Use insulin only	161	25.9	32.5	158	36.2	21.8
Use insulin & oral med	161	24.7	21.2	158	21.2	25.6
Oral med only	161	49.4	46.2	158	42.5	52.6
Number of teeth	157	21.4	20.7	157	21.6	20.6
Gingival Index (mean)	157	0.74	0.77	157	0.72	0.82
CPITN (mean)	157	2.8	2.9	157	2.8	2.8
Recession (mean)	154	0.62	0.75	154	0.63	0.74
Worst recession	154	3.9	4.1	154	4.1	4.0
Mean pocket depth	154	2.5	2.5	154	2.5	2.4
Worst pocket depth	154	5.8	5.7	154	6.0 *	5.5
Mean loss of attachment	154	3.1	3.2	154	3.2	3.1
Worst loss of attachment	154	7.3	7.5	154	7.6	7.2
No. of sites w/pockets > 3mm	154	16.7	16.8	154	17.7	15.9
No. of sites w/pockets > 5mm	154	2.8	3.2	154	3.4	2.7
% sites w/pockets > 3mm	154	13.6	13.9	154	14.8	12.7
% sites w/pockets > 5mm	154	2.5	2.7	154	3.0	2.3
No. of sites Gingival Index = 2, 3	157	2.2	2.2	157	2.0	2.5
% sites Gingival Index = 2, 3	157	13.2	14.3	157	13.0	14.9
No. of teeth w/exudate on palpation	157	0.16	0.30	157	0.34	0.13
% teeth w/exudate on palpation	157	1.0	1.5	157	1.6	1.0
No. of teeth w/exudate on probing	154	0.05	0.12	154	0.09	0.09
% teeth w/exudate on probing	154	0.21	0.65	154	0.38	0.5

*$p < 0.05$.

HbA1c, haemoglobin A1c; BMI, body mass index; sr, self-report; CPITN, Community Periodontal Index of Treatment Need; pockets periodontal pockets.

treatment groups, analyses will be run with and without adjusting for these illnesses. Similarly, peripheral vascular diseases and diabetes with other complications were more common in the 12-month group; thus, analyses will be run with and without adjusting for these illnesses.

Recruitment in clinical trials is time consuming and costly. We experienced the loss of 22% of our potential sample because of a lack of response from primary care providers. One way to increase efficiency would be to ask for primary care provider's concurrence after determining that veterans are both interested and eligible. Also, we initially provided veterans with ''opt-out'' postcards only; we added an ''opt-in'' box after recruiting the first third of patients. The average monthly recruitment rates stabilized after introduction of this feature.

Participants differ in minor ways from the sample frame of all veterans with HbA1c $\geq$ 8.5% in this study. They are younger, with slightly higher HbA1cs and slightly higher prevalences of obesity, drug use, PTSD, depression and bipolar illness. Despite these small differences, the results of this study will be reasonably generalizable to populations beyond veterans with poorly controlled diabetes receiving VA outpatient care.

While we randomized 193 subjects, we then excluded 28 for the reasons shown in Fig. 2 of a separate paper (J. A. Jones, 2006), and then only 154–157 had complete periodontal evaluations. This is an artifact of our study design, a design used in vaccine trials, in that some participants were not actually seen face-to-face until month 4. In order to not contaminate the ''deferred treatment'' group, we did not conduct their baseline examination until the 4-month visit. After exclusions, eight of the initial 165 subsequently withdrew, and three persons, when examined, did not meet our entry criteria; thus, they were excluded after their baseline CPITN. The missing data are reflected in Table 2.

In preliminary analyses, we determined the proportions with periodontal disease of varying definitions and extent

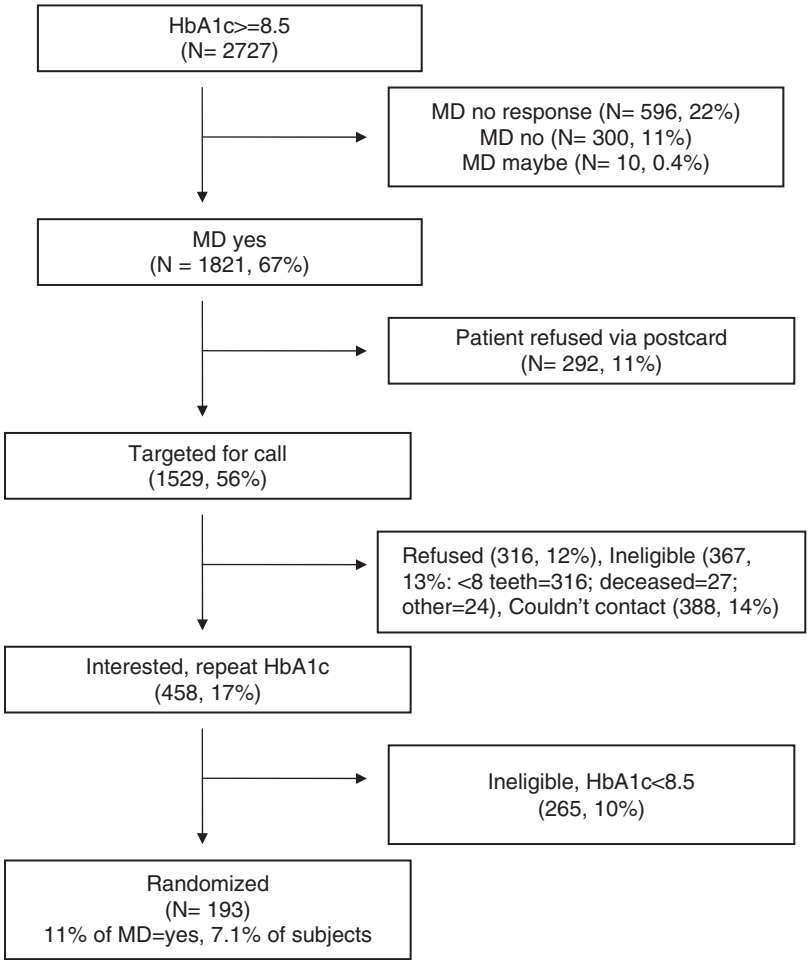

Fig. 2. Recruitment and randomization: VA Dental Diabetes Study.

in a sample of 128 men [mean age of 59 (SD = 11) and mean number of teeth of 21 (SD = 6)] meeting our inclusion criteria. We examined how well our measure for periodontal treatment need correctly identified periodontitis. We defined clinical attachment loss (CAL) as pocket depth plus recession (when present) and examined three case definitions of periodontitis: CAL of 2 mm, CAL of 4 mm, and exudate on palpation or probing. For each definition, we examined four levels of disease extent: one site, two sites, two teeth or two non-adjacent teeth. All participants had CAL $\geqslant 4+$mm at one site, nearly all (99%) had it at two sites, and 97% had it on two non-adjacent teeth. Thus, our inclusion criteria were reasonable in identifying individuals with CAL $\geqslant 4$ on two non-adjacent teeth.

Because of the large number of variables analysed, some of the differences described may have occurred due to chance. If we use the stricter 0.01 as the threshold for significance because of multiple testing, there were no significant differences between study groups or between the randomized participants and the sampling frame, strengthening the confidence in the generalizability and randomization. Further, it is important to note that the differential yield in recruitment may in part be related to the veterans' interests in and/or actual ability to access care. Thus, while the persons enroled may not be representative of all veterans with poorly controlled HbA1c, they may actually be representative of persons with poorly controlled diabetes who would undergo treatment in real-world settings.

In conclusion, the baseline characteristics presented show that it is feasible to conduct a randomized clinical trial in veterans with poorly controlled diabetes and a high illness burden. Relative to the sample frame of patients with HbA1c $\geq$ 8.5%, the overall yield of patients randomized is low (7.1%). While improvement in the overall yield may not be feasible, there are ways to make the process of identifying study subjects more efficient, i.e., use of opt-in/opt-out postcards and only seeking concurrence from the primary care providers *after* the patient expresses interest in participation.

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Clinical Relevance

Scientific rationale: This paper describes the study design, recruitment, and baseline characteristics of a single-blind, controlled clinical trial designed to test the efficacy of periodontal care on glycaemic control in veterans with poorly controlled diabetes.

Principal findings: The study group was similar to the sample frame in this trial, supporting external validity. In addition, there were few differences between study groups with respect to baseline characteristics, overall illness burden severity of diabetes, dental characteristics, and questionnaire data, supporting internal validity.

Practical implications: The results of this trial will yield useful new findings regarding the efficacy of periodontal therapy in diabetes.