Fibromyalgia (FM) affects more than 1 million Americans and is characterized by chronic pain, tender points, and fluctuating severity. The condition is associated with fatigue, nonrestorative sleep, cognitive dysfunction, headaches, anxiety, depression, joint stiffness, dizziness, atypical chest pain, and other symptoms that might interfere with the safe driving of a motor vehicle. Treatment may include exercise, behavioral therapy, analgesia, antidepressants, diet change, sedatives, and anticonvulsants. No blood test or imaging scan can routinely diagnose the condition, gauge case severity, or monitor a patient’s course. FM is an example of an imperfectly understood condition associated with substantial patient suffering and medical uncertainty.

Motor vehicle crashes can be common complications for patients with chronic medical conditions. The blatant damage of a serious crash provides the rationale for health prevention, including warnings by physicians to patients regarding motor vehicle safety. Specific diseases can contribute to crash risk by causing sudden unconsciousness (e.g., narcolepsy), temporary impairment (e.g., chemotherapy), or chronic disability (e.g., dementia). In turn, medical authorities in the United States and elsewhere have developed guidelines for assessing a patient’s fitness to drive. No guidelines, however, address patients with FM although some cautions appear for patients with pain or impaired functional status.

Prior research has investigated whether FM can be a consequence of a past motor vehicle crash; however, the literature contains no data on whether FM could be a contributor to a future motor vehicle crash. We hypothesized that FM might be associated with limitations that compromise a patient’s driving. Neck pain or opioid medications, for
example, may interfere with a motorist’s ability to check blind spots or react quickly.10,11 Moreover, the chronic subjective varying nature of FM might provide insufficient objective feedback for self-regulation of driving12. Our study question was: “Are drivers diagnosed with FM more prone to motor vehicle crashes than the population norm?”

MATERIALS AND METHODS

Population setting. Ontario in 2006 had a population of about 9,949,480 adults, of whom 8,867,965 were licensed drivers involved in a total of 216,247 police-reported crashes13,14. We defined a serious motor vehicle crash as an incident resulting in the driver going to a hospital emergency department, thereby excluding crashes that resulted in minor injury or vehicle damage only. This definition also excluded cases where the patient was a passenger or a pedestrian. For the population of Ontario in 2006, these criteria amounted to 19,507 crashes that sent the driver to a hospital emergency department, equal to an annual event rate of 2.20 serious motor vehicle crashes per 1000 drivers in the general population (19,507 + 8,867,965 x 2,200).

Ontario on April 1, 2006, was distinctive in introducing an additional physician fee (code K037) for dedicated special care of patients diagnosed with FM15,16,17. This was a comprehensive fee code encompassing all common and specific elements of medical care ($51.70) for this diagnosis18. The intent was to provide priority attention for special situations, analogous to physician fee K039 for dedicated smoking cessation counseling19,20. Regardless of dedicated special care for FM, patients had free access to emergency care under universal health insurance and could be tracked over time through validated population-based databases covering all 174 full-service emergency departments in the region19.

Patient selection and diagnosis date. We identified adults diagnosed with FM between April 1, 2006, and March 31, 2012, and excluded individuals younger than age 18 years, living outside Ontario, or lacking valid identifiers under universal health insurance. The 6-year interval was selected to provide all data following the introduction of the dedicated care program and to ensure a minimum 1-year followup for all patients. FM was defined as a physician diagnosis coded by the International Classification of Disease 9th Revision (integer code: 729)22. To reduce false-positive errors, we excluded patients with only a single physician visit for the diagnosis, in accord with past research23. These codes had a sensitivity of 62% to 85% and a specificity of 94% to 99% when validated for other disorders24,25,26,27. The diagnosis of FM, therefore, is prone to false positives, false negatives, and inconsistencies over time28.

FM often has a gradual onset and delayed diagnosis so that the onset is also uncertain. We defined the start of followup for each patient (time-zero) according to the date of a second (confirmed) diagnosis of FM following April 1, 2006. Patients who had 2 or more visits for FM during the prior 5 years were defined as having an ongoing persistent diagnosis (prevalent cases). The remaining patients who had no other visits for FM during earlier years were defined as having an initial new diagnosis (incident cases). The distinction between a persistent and a new diagnosis served as our pre-specified subgroup analysis to examine patients with differing disease durations. The available databases lacked data on diagnostic certainty and severity.

Patient characteristics. Additional diagnoses that are often considered and sometimes misdiagnosed as FM were ascertained from physician billing data for the full year prior to diagnosis29. Psychiatric conditions included depression, anxiety, alcoholism, substance abuse, and posttraumatic stress disorder (codes 296, 300, 303, 304, 305, 308, 309). Rheumatic disorders included systemic lupus erythematosus, rheumatoid arthritis, ankylosing spondylitis, and polymyalgia rheumatica (codes 710, 712, 714, 720, 725, 737). General medical comorbidities included migraine headaches, irritable bowel disorder, hypothyroidism, multiple sclerosis, breast cancer, and endometriosis (codes 042, 043, 044, 070, 170, 244, 340, 346, 564, 617).

RESULTS

Descriptive overview. A total of 137,631 patients were identified, of whom about two-thirds were new cases and one-third were persistent cases. Patients in both groups spanned a broad range of ages and socioeconomic status.
(Table 1). The median patient was a 52-year-old woman (a demographic profile that would otherwise predict crash risks below the population norm). Few patients had a history of an additional rheumatic, psychiatric, or general medical comorbidity (yet more than the population norm). Patients with persistent FM tended to be older, more likely to have a psychiatric diagnosis, and less likely to have an acute injury than patients with a new diagnosis of FM.

**Motor vehicle crashes.** The patients accounted for 1566 serious motor vehicle crashes during the year before diagnosis. This was equal to 11.38 events per 1000 individuals annually and demonstrated a strong reciprocal association where many crashes preceded the diagnosis of FM (Figure 1). The patients also accounted for an additional 738 serious motor vehicle crashes during the subsequent year following diagnosis. This subsequent rate was equal to 5.36 events per 1000 patients annually and was more than twice the population norm. The observed risk during followup equaled an incidence rate ratio of 2.44 (95% CI 2.27–2.63, p < 0.001) and a net increase of 438 crashes compared with the population norm.

**Control patients.** During the same interval, 75,617 other patients were diagnosed with alcoholism and 40,753 other patients were diagnosed with an arm fracture. Those with alcoholism accounted for 395 crashes during the first year following their diagnosis (5.22 events per 1000 patients annually). The observed risk with alcoholism equaled an incidence rate ratio of 2.38 (95% CI 2.15–2.63) and a net increase of 229 crashes compared with the population norm. Those with an arm fracture accounted for 98 crashes during the first year following their diagnosis (2.40 events per 1000 patients annually). The observed risk with an arm fracture equaled an incidence rate ratio of 1.10 (95% CI 0.90–1.34) and no net increase compared with the population norm.

**Individual characteristics.** The increased risk associated with FM was consistent for patients with different characteristics. Each subgroup had a risk more than twice the population norm, except for those who were older than age 60 years, free of comorbid diagnoses, having few outpatient clinic visits, or devoid of prior emergency visits (Table 2). No subgroup had a risk within the population norm. Patients with an emergency visit in the prior year had risks exceeding 3 times the population norm. The increased risk was observed regardless of whether FM was a new or a persistent diagnosis, was sustained for 5 years in the subgroup of patients with extended followup (Figure 2), and was broadly relevant with fewer than 6 patients contributing more than 1 crash in 1 year.

**Dedicated FM care.** A large subgroup (n = 29,007) received dedicated special care for FM. These patients had a high baseline risk amounting to 854 crashes during the 3-year interval preceding special care (9.81 events per 1000 patients annually). Similarly, the patients accounted for 198 crashes annually. The observed risk with alcoholism equaled an incidence rate ratio of 2.38 (95% CI 2.15–2.63) and a net increase of 229 crashes compared with the population norm.

| Table 1. Patient characteristics (n = 137,631). Values are n (%). |
|-----------------|-----------------|-----------------|
| Characteristics                  | New Diagnosis, n = 89,349 | Persistent Diagnosis, n = 48,282 |
| Age, yrs               | ≤ 39 19,435 (22) | 6375 (13) |
|                       | 40–49 21,847 (24) | 11,382 (24) |
|                       | 50–59 21,516 (24) | 14,155 (29) |
|                       | ≥ 60 26,551 (30) | 16,370 (34) |
| Sex                   | Female 60,405 (68) | 35,541 (74) |
|                       | Male 28,944 (32) | 12,741 (26) |
| Home location         | Urban 77,878 (87) | 43,145 (89) |
|                       | Rural 11,441 (13) | 5110 (11) |
|                       | Missing 30 (0) | 27 (0) |
| Socioeconomic status  | Highest 15,579 (17) | 8509 (18) |
|                       | Next to highest 17,367 (19) | 9694 (20) |
|                       | Middle 17,228 (19) | 9491 (20) |
|                       | Next to lowest 18,740 (21) | 10,092 (21) |
|                       | Lowest 20,102 (22) | 10,377 (21) |
|                       | Missing 333 (0) | 119 (0) |
| Comorbidity*          | Rheumatic 5614 (6) | 2819 (6) |
|                       | Psychiatric 28,182 (32) | 16,811 (35) |
|                       | General medical 11,824 (13) | 7096 (15) |
|                       | Acute trauma 27,805 (31) | 12,885 (27) |
| Total care*           | Outpatient clinic ≥ 7 71,753 (80) | 39,913 (83) |
|                       | Emergency department ≥ 1 34,971 (39) | 16,742 (35) |
|                       | Hospital admission ≥ 1 9712 (11) | 4054 (8) |
| Cohort entry**        | Initial yrs 22,755 (25) | 24,923 (52) |
|                       | Subsequent yrs 66,594 (75) | 23,359 (48) |

during the subsequent 1 year following dedicated special care (6.83 events per 1000 patients annually). The observed risk after dedicated care equaled about a one-third relative reduction compared with baseline (Figure 3). This subsequent rate, however, was still substantial, equal to an incidence rate ratio of 3.11 (95% CI 2.70–3.58), and amounted to a net increase of 134 crashes compared with the population norm.

Other clinical interventions. Relatively few patients (n = 3691) received a physician warning about fitness to drive. As expected, these patients had a high baseline risk of a crash and a reduction in the year after the warning (Figure 4). This subsequent rate after a physician warning was equal to an incidence rate ratio of 3.26 (95% CI 2.26–4.78) and a net increase of 18 crashes compared with the population norm. Conversely, most patients (n = 108,089) received an EKG. As expected, these patients had a high baseline risk of a crash, a high risk during the year after the EKG, and no significant reduction when comparing baseline to subsequent intervals (Appendix).

DISCUSSION
We studied over 100,000 patients diagnosed with FM for a minimum 1 year of followup. We found that the risks of a subsequent serious motor vehicle crash were substantial, sustained, potentially modifiable, and twice the population norm. The risks were distinct from the observed reciprocal pattern (Figure 1) in which an earlier motor vehicle crash was followed by a subsequent FM diagnosis (perhaps explained by reverse causality or regression to the mean)39. The risks were unlikely to reflect solely an adverse consequence of treatment because dedicated special care was followed by a reduction in subsequent crashes. Together, the findings suggest that persons diagnosed with FM are at ongoing risk of a subsequent serious motor vehicle crash.

We caution that the data do not indicate that FM caused motor vehicle crashes because patients may differ in multiple ways from the population norm. Potential unmeasured confounders could include ethnicity, comorbidities, care-seeking propensity, psychiatric comorbidity, and use of psychotropic drugs (all not determined in our study). Such confounders might be imbalanced and powerful among patients with FM; hence, the disease might not create the risk and modifying the disease might not mitigate the risk. Collectively, these limitations imply that the observed association between FM and subsequent crashes is a prognostic marker, but not necessarily a causal mechanism. Such limitations are unavoidable because diseases cannot be randomly assigned to patients.

A second possible misinterpretation involves the distinction between relative risk, absolute risk, and modifiable risk. In this setting, for example, a driver’s annual risk of a police-reported crash was about 2.4% for the population norm (216,247 ÷ 8,867,965). A doubling of risk that extended across the full spectrum of severity would equate to an annual
Table 2. Risk of a crash according to patient characteristics. Missing demographic data coded as rural home location and lowest socioeconomic status. Expected counts calculated relative to general population average. 95% CI assumes Poisson distribution of independent events. Values are n unless otherwise specified.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total Patients</th>
<th>Observed Crashes</th>
<th>Expected Crashes</th>
<th>Incident Rate Ratio</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>Full cohort</td>
<td>137,631</td>
<td>738</td>
<td>303</td>
<td>2.44</td>
<td>2.27–2.63</td>
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<tr>
<td>Age, yrs</td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>≤ 39</td>
<td>25,810</td>
<td>233</td>
<td>57</td>
<td>4.10</td>
<td>3.61–4.68</td>
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<td>40–49</td>
<td>33,229</td>
<td>196</td>
<td>73</td>
<td>2.68</td>
<td>2.33–3.10</td>
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<tr>
<td>50–59</td>
<td>35,671</td>
<td>168</td>
<td>78</td>
<td>2.14</td>
<td>1.84–2.50</td>
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<tr>
<td>≥ 60</td>
<td>42,921</td>
<td>141</td>
<td>94</td>
<td>1.49</td>
<td>1.27–1.77</td>
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<td>Sex</td>
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<td>Female</td>
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<td>521</td>
<td>211</td>
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<td>2.26–2.70</td>
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<td>Male</td>
<td>41,685</td>
<td>217</td>
<td>92</td>
<td>2.37</td>
<td>2.07–2.71</td>
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<td>Home location</td>
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<tr>
<td>Urban</td>
<td>121,023</td>
<td>635</td>
<td>266</td>
<td>2.39</td>
<td>2.21–2.58</td>
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<tr>
<td>Rural</td>
<td>16,608</td>
<td>103</td>
<td>37</td>
<td>2.82</td>
<td>2.33–3.44</td>
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<td>Socioeconomic status</td>
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<tr>
<td>Higher</td>
<td>51,146</td>
<td>244</td>
<td>113</td>
<td>2.19</td>
<td>1.92–2.47</td>
</tr>
<tr>
<td>Middle</td>
<td>26,719</td>
<td>132</td>
<td>59</td>
<td>2.25</td>
<td>1.90–2.68</td>
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<tr>
<td>Lower</td>
<td>59,763</td>
<td>362</td>
<td>131</td>
<td>2.75</td>
<td>2.48–3.06</td>
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<td>Rheumatic</td>
<td>8433</td>
<td>43</td>
<td>19</td>
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<td>Psychiatric</td>
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<td>321</td>
<td>99</td>
<td>3.24</td>
<td>2.91–3.63</td>
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<td>General medical</td>
<td>18,920</td>
<td>131</td>
<td>42</td>
<td>3.15</td>
<td>2.66–3.75</td>
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<tr>
<td>Acute trauma</td>
<td>40,690</td>
<td>297</td>
<td>90</td>
<td>3.32</td>
<td>2.96–3.73</td>
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<tr>
<td>Any combination of the above</td>
<td>80,713</td>
<td>530</td>
<td>178</td>
<td>2.99</td>
<td>2.74–3.26</td>
</tr>
<tr>
<td>None of above</td>
<td>56,918</td>
<td>208</td>
<td>125</td>
<td>1.66</td>
<td>1.45–1.91</td>
</tr>
<tr>
<td>Total care</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Outpatient clinic ≥ 7</td>
<td>111,666</td>
<td>648</td>
<td>246</td>
<td>2.64</td>
<td>2.44–2.86</td>
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<tr>
<td>Outpatient clinic ≤ 6</td>
<td>25,965</td>
<td>90</td>
<td>57</td>
<td>1.58</td>
<td>1.29–1.95</td>
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<tr>
<td>Emergency department ≥ 1</td>
<td>51,713</td>
<td>395</td>
<td>114</td>
<td>3.47</td>
<td>3.15–3.84</td>
</tr>
<tr>
<td>Emergency department = 0</td>
<td>85,918</td>
<td>343</td>
<td>189</td>
<td>1.81</td>
<td>1.63–2.02</td>
</tr>
<tr>
<td>Hospital admission ≥ 1</td>
<td>13,766</td>
<td>78</td>
<td>30</td>
<td>2.58</td>
<td>2.08–3.24</td>
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<tr>
<td>Hospital admission = 0</td>
<td>123,865</td>
<td>660</td>
<td>272</td>
<td>2.42</td>
<td>2.24–2.62</td>
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<td>Cohort entry</td>
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<tr>
<td>Initial yrs</td>
<td>47,678</td>
<td>265</td>
<td>105</td>
<td>2.53</td>
<td>2.24–2.86</td>
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<tr>
<td>Subsequent yrs</td>
<td>89,953</td>
<td>473</td>
<td>198</td>
<td>2.39</td>
<td>2.18–2.62</td>
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<td>Fibromyalgia</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New diagnosis</td>
<td>89,349</td>
<td>473</td>
<td>197</td>
<td>2.41</td>
<td>2.20–2.64</td>
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<tr>
<td>Persistent diagnosis</td>
<td>48,282</td>
<td>265</td>
<td>106</td>
<td>2.50</td>
<td>2.21–2.82</td>
</tr>
</tbody>
</table>

Figure 2. Count of motor vehicle crashes for each patient as a driver during 6 years for subgroup with 5 years of observation after diagnosis (n = 47,678). X axis shows time divided into segments of 28 days’ duration with time-zero defined as the day of fibromyalgia (FM) diagnosis. Y axis shows total count of crashes involving the patient as a driver that result in an emergency department visit. Rate for general population shown by horizontal line. Analysis includes all data, so 1 patient might have more than 1 crash over the 6-year timespan. Results show substantial counts that exceed population norm for extended followup interval. Reciprocal association again evident, showing many crashes leading up to diagnosis of fibromyalgia.
Figure 3. Crashes before and after dedicated care. Bar graph shows count of motor vehicle crashes as a driver for each patient over 5 years for subgroup who received dedicated special care following fibromyalgia diagnosis (n = 29,007). X axis shows time divided into segments of 28 days with time-zero defined as the day of first dedicated special care treatment (K037). Y axis shows total count of crashes involving the patient as a driver that result in an emergency department visit. Rate for general population shown by horizontal line. Time line grouped as baseline interval (3 yrs) and subsequent interval (1 yr). Analysis includes all data so 1 patient might have more than 1 crash over the 5-year timespan. Results show relative reduction in motor vehicle crash counts comparing baseline to subsequent interval following dedicated special care.

Figure 4. Crashes before and after physician warning. Bar graph shows count of motor vehicle crashes as a driver for each patient over 5 years for subgroup who received a medical warning about fitness to drive following fibromyalgia diagnosis (n = 3691). X axis shows time divided into segments of 28 days with time-zero defined as the day of first medical warning about fitness to drive by a physician (K035). Y axis shows total count of crashes involving the patient as a driver that result in an emergency department visit. Rate for general population shown by horizontal line. Time line grouped as baseline interval (3 yrs) and subsequent interval (1 yr). Analysis includes all data so 1 patient might have more than 1 crash over the 5-year timespan. Results show reduction in motor vehicle crash counts comparing baseline to subsequent interval following warning.
risk of about 4.8% among drivers with FM (2.4 × 2). A one-third relative risk reduction following dedicated special care, therefore, might reduce this absolute annual risk to about 3.2% (4.8 × two-thirds), mathematically equal to a number-needed-to-treat of about 63 to prevent 1 police-reported crash within 1 year. These estimates of net benefit are based on testable assumptions that could be explored in future research.

Several other limitations also remain as sources of uncertainty. We relied on ICD-9 codes (that are imprecise and overlap other muscular rheumatism disorders), included only patients with a physician diagnosis (which is fallible), and could not ascertain cases that were never diagnosed. Our study did not include passengers or pedestrians involved in the crash. We lacked data on odometers, destinations, diaries, and other indicators of the amount of active driving. The diagnosis of FM is often unclear, diagnostic definitions change over time, and health services data tend to add further vagaries in coding comorbid diagnoses. We lacked data for at-fault analyses and cannot distinguish whether FM might compromise a patient’s ability to avoid a crash caused by someone else.

One strength of our study is to demonstrate a method that has advantages beyond traditional ways for estimating traffic risks. The most widely cited study on the dangers of drunk driving, for example, would fail current standards of evidence-based medicine. Simulator studies tend to yield ambiguous results based on healthy volunteers engaged in artificial tasks with hypothetical risks. Randomized trials are rarely attempted in traffic because of methodological and ethical obstacles. Here we provide a methodological design that is feasible, reasonable, and relevant to an array of diseases that might predispose patients to a motor vehicle crash. Further, we illustrate the methods with a novel finding (linking FM with fitness to drive) that was not previously discovered.

Patients with FM commonly report frustration with physicians, dissatisfaction with care, and exasperation with standard biomedical paradigms for their situation. An overly patronizing approach to motor vehicle traffic safety, therefore, might further compromise a doctor-patient relationship and lessen patient well-being. At present, physician warnings for medically unfit motorists can be effective for improving driving safety in older patients and are mandatory in several regions of North America. Clinical judgment is needed in the remaining locations when deciding whether the crash risks associated with FM merit a tactful warning in a compassionate manner to improve driving safety and maintain patient health.

ACKNOWLEDGMENT
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43. Borkenstein RF, Crowther RF, Shumate RP, Ziel WB, Zylman R. The role of the drinking driver in traffic accidents. Bloomington, Indiana: Department of Police Administration, Indiana University; 1964.
APPENDIX 1. Crashes before and after electrocardiogram (EKG). Bar graph of count of motor vehicle crashes as a driver for each patient over 5 years for subgroup who received an EKG following fibromyalgia diagnosis (n = 108,089). X axis shows time divided into segments of 28 days with time-zero defined as the day of first EKG (G313). Y axis shows total count of crashes involving the patient as a driver that result in an emergency department visit. Rate for general population shown by horizontal grey line. Timeline grouped as baseline interval (3 yrs) and subsequent interval (1 yr). Analysis includes all data, so 1 patient might have more than 1 crash over the 5-year timespan. Results show no reduction in motor vehicle crash counts comparing baseline with subsequent interval following EKG.