SYSTEMIC REVIEWS/META-ANALYSIS

Systematic review of the evidence for Trails B cut-off scores in assessing fitness-to-drive



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ABSTRACT

Background

Fitness-to-drive guidelines recommend employing the Trail Making B Test (a.k.a. Trails B), but do not provide guidance regarding cut-off scores. There is ongoing debate regarding the optimal cut-off score on the Trails B test.

The objective of this study was to address this controversy by systematically reviewing the evidence for specific Trails B cut-off scores (e.g., cut-offs in both time to completion and number of errors) with respect to fitness-to-drive.

Methods

Systematic review of all prospective cohort, retrospective cohort, case-control, correlation, and cross-sectional studies reporting the ability of the Trails B to predict driving safety that were published in English-language, peer-reviewed journals.

Results

Forty-seven articles were reviewed. None of the articles justified sample sizes via formal calculations. Cut-off scores reported based on research include: 90 seconds, 133 seconds, 147 seconds, 180 seconds, and < 3 errors.

Conclusions

There is support for the previously published Trails B cut-offs of 3 minutes or 3 errors (the '3 or 3 rule'). Major methodological limitations of this body of research were uncovered including (1) lack of justification of sample size leaving studies open to Type II error (i.e., false negative findings), and (2) excessive focus on associations rather than clinically useful cut-off scores. Key words: Trail Making Test, Trails B, driving, fitness-todrive, cut-off

INTRODUCTION

Physicians in most Canadian jurisdictions are legally mandated to report medical findings that could impact on fitnessto-drive (http://www.cma.ca/driversguide).⁽¹⁾ Even where reporting is not mandatory, physicians can still potentially be found liable if they fail to report a patient who harms others due to a car crash attributed to their medical impairments.⁽²⁾ On a more positive note, the reporting of medical findings that could impact on fitness-to-drive also represents an opportunity to fulfill an important societal role; assessments of fitness-to-drive allow physicians to help their patients avoid disabling injury or death and also to help patients and their families avoid the grief and legal repercussions associated with contributing to the injuries or deaths of other road users or bystanders.⁽²⁾

Driving guidelines such as those of the Canadian Medical Association, the Canadian Council of Motor Transport Administrators, the Driver and Vehicle Licensing Agency in the United Kingdom, and the American Medical Association recommend the Trail Making B Test (a.k.a. Trails B) to assess fitness-to-drive.^(1,3,4,5) Trails B tests dual attention (cognitive flexibility in switching attention between two competing static sets of stimuli which is a much lower level of cognitive demand than switching between multiple moving stimuli encountered when driving) and executive function. Driving represents a "super-Instrumental Activity of Daily Living (super-IADL)" or "super-executive function" that can result in death if performed incorrectly or too slowly-this, along with the risk to others, makes it unique among IADLs or executive functions. Unfortunately, guidelines rarely advise physicians regarding which Trails B findings indicate unfitness-to-drive.

A study by Tombaugh⁽⁶⁾ of the normative values of the Trails B test demonstrated that the mean time to complete Trails B is < 180 seconds for all age groups. There were

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some outliers whose scores exceeded 180 seconds; the lowest 20th percentile in the 80 to 84 age group and the lowest 30th percentile in the 85 to 89 age group, but the validity of the latter findings is questionable given the small sample size in these age-specific cells. It is also possible that some of these findings do not represent true normative values (i.e., values for persons without diseases or drugs affecting the results), but may represent hidden disease or hidden medication effects. ⁽⁷⁾ Even if these are true norms for healthy people, being in a normative range may not necessarily mean the patient is safe to drive. We have to accept reality—as people get older, they do not have more time to stop their cars or to respond to emergencies. Physical laws do not change according to age. We must, therefore, remain very skeptical of age-adjusted norms for tests used to screen for fitness-to-drive.⁽⁷⁾

Continuing medical education articles have recommended a Trails B cut-off of 180 seconds or three errors (i.e., 3 minutes or 3 errors; the '3 or 3 rule').^(2,7,8) Given the findings of Tombaugh,⁽⁶⁾ indicating the scores of the lowest 20th percentile in the 80 to 84 year-old group and the lowest 30th percentile in the 85 to 89 year-old group exceeded 180 seconds, some have recommended caution in employing a strict 180 second cut-off. There is ongoing debate in the field of research into the evaluation of fitness-to-drive regarding the optimal cut-off score on the Trails B test.

The objective of this study was to address this controversy by systematically reviewing the evidence for specific Trails B cut-off scores (e.g., cut-offs in both time to completion and number of errors) with respect to fitness-to-drive.

METHODS

This systematic review was conducted in accordance with the process and methods recommended by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.⁽⁹⁾

The need for ethics approval was waived for this study by the Ottawa Hospital Research Ethics Board, as it only involved a literature search.

Literature Search

An electronic literature search was conducted using CINAHL, Cochrane Database of Systematic Reviews, EMBASE, MEDLINE, PsycINFO, PubMed, and Scopus databases for all relevant English-language publications. No starting date restriction was used in this search. The most updated search was conducted in November 2012. Relevant articles were retrieved using the following subject headings and keywords in various combinations: Trail Making Test, Trail Making Test B, Trail Making B, Trail Making Test Part B, Trail Making Test A and B, Trail Making Test Parts A & B, Trail Making Test Parts A and B, Trails B, TMT, TMT-B, drive/driving/ driver, auto/automobile, car, vehicle/motor vehicle, accident, traffic, crash, collision, MVA and MVC. This electronic search was supplemented by hand searching of the reference lists of selected articles, meta-analyses, and review articles.

Inclusion and Exclusion Criteria

All prospective cohort, retrospective cohort, case-control, correlation, and cross-sectional studies reporting the ability of the Trails B test (i.e., the standard Arabic numerals version employing numbers 1–13 and letters A–L) to predict driving safety were included.

The systematic review was restricted to articles presenting original research findings published in English-language, peerreviewed journals. Reviews, meta-analyses, commentaries, editorials, consensus statements, and guidelines were searched for references, but were not included in the systematic review.

Data Extraction

Data extraction forms included publication details, investigative site locations, source of participants, design type, sample size, whether power and sample size calculations were provided, age of participants, diseases included (e.g., Alzheimer's Disease, Parkinson's Disease, stroke, traumatic or anoxic brain injury etc.), method of evaluating driving safety (e.g., simulator, on-road, questionnaire, record of crashes), reported associations of Trails B with predicting driving safety, whether a cut-off was reported for Trails B, and source of reported cut-off (study analysis or reference).

Two investigators (MR, FM) independently extracted data from all included studies, and then met to identify and discuss discrepancies in extracted data. Disagreements between the reviewers were discussed and a consensus agreement was reached.

Since Trails B is not routinely employed as part of a multivariate equation in clinical practice, we focused on univariate associations (i.e., the score of the Trails B in isolation, not as part of a multivariate equation).

RESULTS

Figure 1 illustrates the process of selection of articles for the systematic review. After reviewing 97 articles in detail, including a hand search of the reference sections, a total of 47 articles met the inclusion criteria to be systematically reviewed. Study characteristics are presented in Table 1. The primary outcome (i.e., measures of driving safety) was history of crash (reported or recorded) for 10 (21.3%) studies, simulator test score for 10 (21.3%) studies, and on-road assessment for 27 (57.4%) studies.

Table 2 shows the associations of Trails B with predicting driving safety (primary outcome), organized according to sample sizes in ascending order. Trails B was positively associated with determining fitness-to-drive in 32 out of 47 (68.1%) studies and found to have no association in 15 (31.9%) studies.

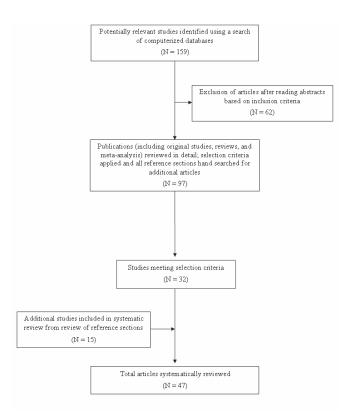


FIGURE 1. Article selection flow diagram

None of the studies justified sample sizes via formal calculations. The sample sizes of many of the studies were small, with 24 (51.1%) studies having fewer than 100 participants (Table 2). Eleven of these 24 studies with N < 100 did not find an association of Trails B with driving safety. Stated another way, of the 15 studies showing no association (shaded in gray in Table 2), 11 (73.3%) had small sizes of \leq 100. The remaining four studies with no association had sample sizes of 144, 155, 176, and 1,876.

Table 3 shows the studies that reported cut-off values for Trails B in predicting fitness-to-drive. Eight of the 47 studies (17.0%) reported cut-off values for Trails B from various sources. Five of these studies reported cut-off values derived from analysis of their data (i.e., primary research): 90 seconds,⁽¹⁰⁾ 133 seconds,⁽¹¹⁾ 147 seconds,⁽¹²⁾ 180 seconds,⁽¹³⁾ and < 3 errors.⁽¹⁴⁾

Three studies reported cut-off values from references cited within their papers: 180 seconds (3 minutes)^(15,16) and \geq 292 seconds.⁽¹⁷⁾ Two of these references (Table 3) are not original research,^(18,19) and the remaining three references are not driving studies.^(6,20,21) The 292 second cut-off was derived from a neuropsychology textbook,⁽²²⁾ not a driving study.

Therefore, in addition to the three continuing medical education articles^(2,7,8) recommending a 3 minute or 3 error cut-off (the '3 or 3 rule'), this systematic review uncovered four additional articles supporting this cut-off ^(15,13,16,14) and

three other studies recommending even shorter time cut-offs ranging from 90 seconds to 147 seconds.^(10, 11, 12)

DISCUSSION

Some have argued that no in-office tests can determine fitnessto-drive in all situations. This statement is correct, but is often misinterpreted as meaning in-office tests can never be used to determine fitness-to-drive in any situation. While it is obvious that no single in-office tests can be expected to be able to determine fitness-to-drive in all situations, it is a fundamental error in logic to assume therefore that in-office tests cannot determine fitness-to-drive in some situations.

To illustrate the point, as performance on tests such as Trails B progressively worsens with longer completion times and/or more errors, then clinicians should become increasingly comfortable stating a patient "has a potential functional impairment that may increase the risk of crash". For instance, if a patient took 10 minutes to complete Trails B and made ten errors with no concerns regarding the validity of the test, then most physicians would likely feel justified in sending this information to their Ministry of Transportation as a finding that could impact on fitness-to-drive.

The extreme findings described above represent situations in which physicians can determine fitness-to-drive using in-office tests. Situations in which deficits are less glaring are more challenging. One way to address more borderline situations is for physicians to carefully consider precisely what they are being asked to evaluate. In Ontario, Canada, the Highway Traffic Act requires the following:

203. (1) Every legally qualified medical practitioner shall report to the Registrar the name, address and clinical condition of every person sixteen years of age or over attending upon the medical practitioner for medical services who, in the opinion of the medical practitioner, is suffering from a condition that may make it dangerous for the person to operate a motor vehicle. R.S.O. 1990, c. H.8, s. 203.⁽¹⁾

In Ontario, physicians are not asked to determine fitnessto-drive (i.e., they are not asked to report patients as fit or unfit to drive), but rather are asked to report findings that may make it dangerous for the person to drive. The Ministry of Transportation retains responsibility for the final determination of fitness-to-drive. When viewed from this perspective, when selecting Trails B cut-offs that may indicate functional impairment that may impact on fitness-to-drive rather than as a final determination of fitness-to-drive, then Trails B cut-offs of 3 minutes or 3 errors (the '3 or 3 rule') remain reasonable to consider when deciding whether or not to bring findings to the attention of the Ministries of Transportation. It is entirely appropriate that the Ministries of Transportation remain responsible for the final determination of fitness-to-drive rather than off-loading their responsibility on MDs.

	Characteristics of included studies						
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety	
Adult Driver (no age restriction)	Betz, 2009 (U.S.) ⁽¹⁵⁾	A study at a single Emergency Depart- ment at a tertiary care center. TMT B and a survey of health sta- tus and driving habits were administered. Time to complete TMT B was com- pared to published norms.	A convenience sample of patients from the Emergency Depart- ment. Participants did not have to be currently driving to be included in the study.	144	Mean 59 Range 18–95	Self-reported MVCs	
	Elkin-Frankston, 2007 (U.S.) ⁽²³⁾	A study to examine the use of the Colour Trails Tests 1 and 2, compared to Trails A and B, in the as- sessment of driver competence.	Participants were recruited through a driving assessment program. All partici- pants were referred for evaluation of driving competence by friends, family members, and physicians.	29	Mean 76.6 ± 9.5	On-road testing	
	Niewoehner, 2012 (U.S.) ⁽³⁰⁾	A study to develop a screening battery for office-based clini- cians to assist with deciding who should proceed to road test- ing in adults with cognitive or visual deficits.	Recruited from a driv- ing evaluation clinic at a Veterans Affairs Medical Centre.	77	Mean 67.8 ±18.4 Range 23–91	On-road testing	
Older Driver (age ≥ 55)	Petrakos, 2009 (U.S.) ⁽³¹⁾	A study to describe driving habit charac- teristics of older driv- ers referred for formal driving evaluation and to compare habits of drivers found to be unsafe to drive with those of safe and restricted drivers.	A sample from a driv- ing evaluation clinic to where subjects had been referred from DMV, family physi- cians, law enforcement and family members. All were either cur- rent drivers or their licenses were recently suspended.	57	Mean 78.5 ± 7.0	Simulator score	

TABLE 1.	
Characteristics of included	studies

	Author, Year	Description of	Continued Description of	Sample Size	Age in Years	Mathod of
	(Country)	Description of Study	Participants	Sample Size	Age in Tears (Mean ± SD, Range)	Method of Evaluating Driving Safety
Older Driver (age ≥ 55)	Freund, 2008 (U.S.) ⁽³²⁾	A study to describe a population of older drivers with driving restrictions, their most common restric- tions, and to compare restricted drivers to their safe and unsafe counterparts.	Participants from a driving clinic referred by physicians, family, friends, DMV, or self referred. All had a valid driver's license.	108	Safe group: Mean 77.63 ± 6.62 Range 62-86 Restricted group: Mean 78.06 ± 8.64 Range 60-99	Simulator score
					Unsafe group: Mean 76.98±7.60 Range 62–97	
	Freund, 2008 (U.S.) ⁽³³⁾	A study to assess to what extent specific cognitive functions contribute to pedal errors among older drivers.	Participants recruited through a driving evaluation clinic, referred by family physicians, DMV, or self referred. All were currently driving.	176	Mean 76 Range 65–89	Simulator score
	Wood, 2008 (Aus- tralia) ⁽³⁴⁾	A study to identify a battery of tests that predicts safe and unsafe performance on an on-road assess- ment of driving.	Participants were community-dwelling individuals ≥ 70 years old who were living independently without walking aids. They were recruited through the electoral roll to participate in a larger study. Those who were current drivers were invited to participate in this study.	270	Mean 75.8 ± 4.0 Range 70–88	On-road test- ing
	Ball, 2006 (U.S.) ⁽¹²⁾	A study to evaluate the relationship be- tween performance- based risk factors and subsequent, future at-fault motor vehicle collision involvement in a cohort of older drivers.	Participants were older adults (≥ 55 years old) presenting to renew their driver's license at MVA offices. This is a similar population to the MaryPODS study – see below.	1,910	Mean 68.55 ±7.95 Range 55–96	Database MVCs

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	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
Older Driver (age ≥ 55)	Kantor, 2004 (U.S.) ⁽²⁹⁾	A study to identify elements of an older driver evaluation program that predict driving performance in older adults.	Participants were referred to the Older Driver Evaluation Pro- gram by physicians, other health profes- sionals, and family members.	664	No mean, SD, or range provided The only comment on age of participants was: "65% of all participants were over age 70".	On-road testing
	Staplin, 2003 (U.S.) ^{(13);} Staplin, 2003 (MaryPODS) ⁽³⁵⁾	(1) "Model Driver Screening and Evalu- ation Program Final Technical Report, Maryland Pilot Older Driver Study (MaryPODS)": A study to analyse the relationships between functional capac- ity measures and future at-fault crash involvement for older drivers. The analyses were based on driving history data bracket- ing each individual's test date by one year retrospectively, and, on average, slightly under 2 years pro- spectively.	Participants were recruited from Motor Vehicle Administra- tion (MVA) offices. All persons age ≥ 55 appearing on random days for were asked to volunteer.	1,876	Mean 68.28 ±_7.92 Range 55–96	Database MVCs
		 (2) "MaryPODS Revisited: Updated Crash Analysis and Implications for Screening Program Implementation": Previous analyses was updated to include one additional year of driving experience. 	Participants were recruited from MVA offices. All persons age ≥ 55 appearing on random days for were asked to volunteer.	1,876	Mean 68.28 ± 7.92 Range 55–96	Database MVCs

TABLE 1.

			Continued			
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
$Older Driver (age \ge 55)$	Szlyk, 2002 (U.S.) ⁽³⁶⁾	A study to select a neuropsychological battery that correlated with driving simulator skills. Administered MMSE scores served as a criterion cut-off for placement into a group with suspected dementia or a group of control subjects.	Participants were recruited from Dept. of Veteran Affairs, memory clinics, and a geriatric clinic. All had driving experience in the past 2 years.	N = 22 Cases (suspected dementia) = 8 Controls (normal cognition) = 14	Cases: Mean 75.6 ± 7.0 Range 67-85 Controls: Mean 77.0 ± 6.2 Range 70-91	Simulator score
	Stutts, 1998 (U.S.) ⁽³⁷⁾	A study to investi- gate the usefulness of 5 brief tests of cognitive function for identifying older driv- ers who may be at in- creased risk of crash involvement. For each driver, crashes and convictions were tallied from a driver history file over the 3-year period im- mediately prior to license assessment.	All drivers ≥ 65 years old applying for driv- er's license renewal between 1994-95 were invited to participate.	3,238	Mean 73.6; SD and range not provided	Database MVCs
	Cushman, 1996 (U.S.) ⁽³⁸⁾	A study to evaluate change in drivers' cognitive abilities and how this impacts driver safety by means of cognitive testing and on-road driving evaluations.	Two groups of partici- pants. The first group were 91 drivers over age 55 recruited from the community. The second group were 32 drivers with early AD referred from the Alzheimer Clinic or Older Adults Clinic.	123	Not reported	On-road testing
	Classen, 2008 (U.S.) ⁽¹⁶⁾	A study to determine the relationship between clinical variables (demo- graphics, cognitive testing, comorbidities, and medications) and failing a standardized road test in adults aged 65 and older.	Participants were recruited via advertise- ments in the com- munity. There were 3 waves of recruitments: one recruiting healthy older adults, another recruiting older adults with multiple comor- bidities, and a third recruiting older adults with movement disor- ders, specifically PD.	127	Mean 74.8 ± 6.3	On-road testing

TABLE	1.	

			Continued			
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
$Older Driver (age \ge 55)$	Tarawneh, 1993 (U.S.) ⁽³⁹⁾	A 2-year study to evaluate the correla- tion between driving performance and measured physical and mental character- istics of older drivers.	Participants were paid volunteers who were active drivers between the ages of 65 and 88.	105	Mean 71.4 Range 65–88	On-road testing
	Marottoli, 1998 (U.S.) ⁽¹¹⁾	A study to develop a battery of tests (visual, cognitive, and physical) relevant to driving which can be performed in a clinician's office and to determine which of these tests were associated with self-reported adverse driving events over 5 years.	Participants were a survival cohort from a previous study, the Project Safety cohort, consisting of a probability sample of noninstitutionalized, actively driving indi- viduals aged 72 years and older.	125	Mean 81.4; SD and range not provided	Self-report
	Emerson, 2012 (U.S.) ⁽⁴⁰⁾	A study to develop predictive models for real-life driving outcomes in older drivers. Participants were followed for 3-7 years for driving outcomes.	Healthy volunteers recruited from the community via ads and announcements.	100	Mean 72.7 ± 5.03 Range 65.3–89	Self-report and Database MVCs
	Rozzini, 2012 (Italy) ⁽⁴¹⁾	A study to examine the usefulness of spe- cific neurocognitive tests for predicting crash involvement in participants aged 80 or older.	Participants were aged ≥ 80 needing to renew their licence at a neuropsychological clinic. In Italy, neuro- psychological tests are required for octogenar- ians wishing to renew their licence.	297	Mean for "non-crash involved" group = 82.8 ± 2.8 Mean for "crash involved" group $= 82.6 \pm 3.3$	
	O'Connor, 2010 (U.S.) ⁽⁴²⁾	A study to evaluate the effectiveness of an interview- based screening tool (including crash his- tory, family concerns, clinical condition, and cognitive function) in identifying at-risk older drivers.	Recruited from a clini- cal driving evaluation program.	160	Mean 78.3; SD and Range not provided	On-road testing

TABLE	1.	

			Continued			
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
Older Driver (age ≥ 55)	Park, 2011 (Korea) ⁽⁴³⁾	A study to find an association between cognitive-perceptual problems of older drivers and unsafe driving performance during driving on a simulator.	Cases recruited from a driver evaluation clinic. Source of con- trols unclear.	N = 103 Cases (age \geq 65) = 55 Controls (age late 20's to early 40's) = 48	Cases: Mean 69.91 ± 3.63 Controls: Mean 34.25 ± 3.62	Simulator score
	Selander, 2011 (Sweden) ⁽⁴⁴⁾	A study to investigate driving errors charac- teristic for older driv- ers and relationships between cognitive off-road and on-road test results.	Older drivers (age 65+) randomly selected from Vehicle Registration Office. Participation volun- tary.	85	Mean 72 ± 5.3 Range 65–85	On-road testing
<i>Alzheimer</i> <i>Disease</i>	Dawson, 2009 (U.S.) ⁽⁴⁵⁾	A study to measure the association of cognition, visual perception, and motor function with driving safety in AD.	AD patients were recruited from a registry maintained by the Dept. of Neurology. Controls were volunteers in the local community, with no neurological diagnosis or complaints and no personal or family report of abnormal cognitive decline. All were active drivers.	N = 155 Cases (probable early dementia) = 40 Controls (neurologically normal) = 115	Cases: Mean 75.1 ± 7.7 Controls: Mean 69.4 ± 7.0	On-road testing
	Grace, 2005 (U.S.) ⁽⁴⁶⁾	A study to examine neuropsychological and motor deficits in PD that may contribute to driving impairment, comparing patients with PD to patients with AD and to healthy elderly controls.	PD patients were drawn consecutively from a hospital-based movement disorders clinic. AD patients were recruited through a hospital-based memory disorders clinic. Control subjects were age and education matched community volunteers or nondemented spouses of AD patients. All participants were currently driving.	N = 62 PD group = 21 AD group = 20 Controls = 21	PD: Mean 68.1 ± 8.5 Range 45-83 AD: Mean 70.8 ± 7.1 Range 59-85 Controls: Mean 69.0 ± 10.4 Range 46-85	On-road testing

	Continued						
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety	
Alzheimer Disease	Rizzo, 1997 (U.S.) ⁽⁴⁷⁾	A study to examine the effect of AD on driver collision avoidance using a driving simulator, and how these unsafe events are predicted by visual and cognitive factors sensitive to decline in aging and AD.	AD patients were recruited from a registry in the AD Research Center of the Dept. of Neurology. Control subjects were volunteers in the local community. All participants held a current driver's license, although some had reduced driving activity due to self or family-imposed restrictions.	N = 39 AD group = 21 Controls = 18	AD: Mean 71.5 ± 8.5 Controls: Mean 71.9 ± 5.5	Simulator score	
	Fox, 1997 (Australia) ⁽⁴⁸⁾	A study to examine driving competence in drivers diagnosed with probable AD using on-road testing and to examine the validity of a standardized medical exam, MMSE, and neuropsychological assessment as predictors of open road driving performance.	Subjects had a diagnosis of probable AD and were consecutively referred for driver assessment from specialist Dementia Clinics. All subjects, except one, were still driving.	19	Mean 74.3 ± 6.4 Range 59–84	On-road testing	
	Rizzo, 2001 (U.S.) ⁽⁴⁹⁾	A study to test whether drivers with mild to moderate AD are at greater risk for intersection crashes compared to normal controls.	AD patients were recruited from a registry in the AD Research Center. Control subjects were volunteers in the local community. All held a valid driver's licence, although some had reduced driving due to self or family-imposed restrictions.	N = 30 AD group = 18 Controls = 12	AD: Mean 73 ± 7 Controls: Mean 70 ± 4.7	Simulator score	

	Continued					
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
Alzheimer Disease	Ott, 2003 (U.S.) ⁽⁵⁰⁾	A study to compare a 4-point caregiver rating scale of driving ability to a battery of standard neuropsychological tests given to subjects with questionable or mild dementia. Based on the results of Part A, a follow up study (Part B) was conducted with only Proteus Mazes in normal subjects and those with mild to moderate dementia. Only Part A of this study contained Trails B, so only Part A methods and results will be presented in this systematic review.	In Part A, patients were drawn from a Memory Disorders Clinic. All had probable AD by NINCDS-ADRDA criteria. In Part B, subjects were drawn from another Memory Disorders Clinic, and this sample consisted of both normal subjects and those with mild–moderate dementia based on CDR criteria.	27	Mean 74.8 ± 5.9	Four-point driving ability rating scale completed by caregiver or family member.
	Uc, 2005 (U.S.) ⁽⁵¹⁾	A study to assess visual search and recognition of roadside targets and safety errors during a landmark and traffic sign identification task in driver with AD compared to neurologically normal older adults.	Participants with mild AD consistent with NINCDS-ADRDA criteria were recruited from a registry in the Dept. of Neurology. Controls were volunteers in the local community. All participants were still driving, although some had reduced driving activity due to self or family-imposed restrictions.	N = 170 AD group = 33 Controls = 137	AD: Mean 76.1 \pm 6.3 Controls: Mean 64.3 \pm 11.4	On-road testing

TABLE 1. Continued

	Continued					
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
Alzheimer Disease	Uc, 2006 (U.S.) ⁽⁵²⁾	A study to test rear-end collision avoidance in mild AD compared with elderly controls using a driving simulator.	Subjects with mild AD (based on NINCDS- ADRDA criteria) were recruited from a registry in the Dept. of Neurology. Control participants were neurologically normal adults volunteering from the local community. All were active drivers, although AD subjects reported significantly less driving activity due to self or family- imposed restrictions.	N = 176 Cases = 61 Controls = 115	Cases: Mean 73.5 ± 8.5 Controls: 69.4 ± 6.7	Simulator score
	Ott, 2008 (U.S.) ⁽⁵³⁾	A study to examine the ability of computerized maze test performance to predict road test performance of cognitively impaired and normal older drivers.	Cases recruited from a Memory Assessment Program and a Memory Disorders Center. Controls recruited from participants' family and friends.	N = 121 Cases (probable or possible AD) = 76 Controls (without cognitive impairment) = 45	Cases: Mean 75.8 ± 6.9 Controls: Mean 73.6 ± 9	On-road testing
Parkinson's Disease	Uc, 2006 (U.S.) ⁽²⁵⁾	A study to assess the ability for visual search and recognition of roadside targets and safety errors during a landmark and traffic sign identification task in drivers with PD.	Patients with mild to moderate PD were recruited from Movement Disorders clinics. Control subjects were neurologically normal elderly adults. All participants were community-dwelling, independently living, and licensed active drivers.	N = 230 Cases (mild to moderate PD) = 79 Controls (neurologically normal elderly adults) = 151	Cases: Mean 65.9 ± 8.6, Controls: 65.3 ± 11.5	On-road testing

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	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
Parkinson's Disease	Grace, 2005 (U.S.) (46)	A study to examine neuropsychological and motor deficits in PD that may contribute to driving impairment, comparing patients with PD to patients with AD and to healthy elderly controls.	PD patients were drawn consecutively forma hospital-based movement disorders clinic. AD patients were recruited through a hospital-based memory disorders clinic. Control subjects were age and education matched community volunteers or nondemented spouses of AD patients. All participants were currently driving.	N = 62 PD group = 21 AD group = 20 Controls = 21	PD: Mean 68.1 ± 8.5 Range 45-83 AD: Mean 70.8 ± 7.1 Range 59-85 Controls: Mean 69.0 ± 10.4 Range 46-85	On-road testing
	Scally, 2011 (Australia) ⁽²⁶⁾	A study to investigate the impact of external cue validity on simulated driving performance in PD compared to controls.	Cases were drivers with PD diagnosed by a neurologist. Source of cases and controls not explicitly stated.	N = 28 Cases (with PD) = 19 Controls (healthy, age- matched) = 19	Cases: Mean 68.74 \pm 6.72 Range 52–81 Controls: Mean 68.05 \pm 7.2 Range 56–78	Simulator score
Dementia, not specified	Carr, 2011 (U.S.) ⁽⁵⁴⁾	A study to develop a cognitive and functional screening battery for the on- road performance of older drivers with dementia.	Recruited from a driving evaluation clinic. Participants had a diagnosis of dementia from physician referral or from AD-8 (Aging and Dementia-8) questionnaire completed by an informant.	85	Mean 74.2 ±9 Range 52–90	On-road testing
Questionable Dementia (CDR = 0.5) including possible AD, stroke, remote history of alcohol abuse, or head trauma	Whelihan, 2005 (U.S.) ⁽⁵⁵⁾	A study to investigate the role of visual attention and executive measures in predicting driving competence in older individuals with early-stage cognitive decline compared to age-matched controls.	Participants in the patient group all had a CDR of 0.5 and were recruited sequentially from a Memory Disorders Clinic. Controls all had a CDR of 0 (cognitively intact) and were recruited from the local community via ads.	N = 46 Questionable dementia group (CDR 0.5) = 23 Controls (CDR 0) = 23	Cases: Mean 78.2 ± 9.3 Controls: Mean 74.3 ±7.3	On-road testing

TABLE 1.

			Continued			
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
Acquired Cognitive Impairment after Traumatic Brain Injury, Stroke, Hemorrhage, Encephalitis, Tumour, or other	Alexandersen, 2009 (Norway) ⁽⁵⁶⁾	A study to investigate the predictive value of neuropsychological tests for on-road evaluation outcome after inconclusive assessment.	Outpatients at Dept. of Physical Medicine and Rehabilitation referred for evaluation of fitness to drive after inconclusive neuropsychological assessment.	35	Mean 47.4 ± 13.7	On-road testing
CNS disorders (e.g., Multiple Sclerosis, Huntington Disease)	Lundqvist, 2007 (Sweden) ⁽⁵⁷⁾	A study to assess drivers with acquired brain injury on cognitive functions, driving performance, and the drivers'self- rating of their driving.	The participants were a consecutive sample of patients with brain injury who received outpatient rehabilitation services at the Dept. of Rehabilitation Medicine.	30	Mean 51.6 ± 11.21 Range 21–75	On-road testing
	Mazer, 1998 (Canada) ⁽¹⁴⁾	A study to determine the ability of perceptual testing to predict on-road driving outcome in subjects with stroke.	Subjects with stroke referred to a Driving Evaluation Service, including both inpatients at a Rehabilitation Hospital and outpatient referrals.	84	Mean 60.8 ± 11.9 Range 27–84	On-road testing
	Devos, 2012 (Belgium) ⁽⁵⁸⁾	A study to identify the most accurate clinical predictors of fitness to drive in HD.	Cases were all active drivers recruited from HD clinic at a university hospital. Source of controls not clear.	N = 60 Cases (with HD) = 30 Healthy controls = 30	Cases: Mean 50.2 ± 12.4 Controls: Mean 50.26 ± 12.64	On-road testing
	Bliokas, 2011 (Australia) ⁽¹⁷⁾	A study to evaluate a neuropsychological assessment battery and its individual test components to assess fitness to drive in cognitively impaired individuals (including traumatic brain injury, stroke, PD, dementia).	Participants were referred for driving assessment after neurological injury to a Brain Injury Service and Rehab Unit.	104	Mean 61.35 ± 16.71 Range 17–93	On-road testing

			TABLE 1. Continued			
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety
Acquired Cognitive Impairment after Traumatic Brain Injury, Stroke, Hemorrhage, Encephalitis, Tumour, or other CNS disorders (e.g., Multiple Sclerosis, Huntington Disease)	Soderstrom, 2006 (Sweden) ⁽⁵⁹⁾	A study to examine the predictive value of a neuropsychological test battery relating to an on-road driving evaluation in patients with stroke and to determine whether patients who failed the evaluation could improve their driving through behind-the- wheel training.	Cases were patients admitted consecutively to hospital for stroke. All had valid licence. Interval between stroke onset and examination ranged from 1.4 to 14 months. Healthy controls were recruited via ad in newspaper.	N = 54 Cases (with stroke) = 34 Controls = 20	Range for all subjects = 25-67 Cases: Mean 54 ± 8.8 Controls: Mean and SD not reported	On-road testing
Acquired Brain Injury (Traumatic Brain Injury, Anoxic Brain Injury, Stroke)	Hartman-Maier, 2008 (Israel) ⁽²⁴⁾	A study to examine the validity of the Colour Trails Test in the pre-driver assessment of individuals with acquired brain injury (including traumatic brain injury, anoxic brain injury, stroke).	Participants with acquired brain injury were selected from a pool of clients referred to a driving rehabilitation program within the Occupational Therapy Dept. at a central medical center.	30	Mean 57.97 ± 18.05 Range 20–80	On-road testing
	Hargrave, 2012 (U.S.) ⁽¹⁰⁾	A study to examine the utility of the Frontal Assessment Battery and the Trail Making Test B in predicting on-road driving performance after stroke or traumatic brain injury.	Participants were referred for driving assessment after diagnosis of stroke or traumatic brain injury to a driving rehab program.	76	Mean 57.3 ± 17 Range 18–87	On-road testing
	Lundqvist, 2008 (Sweden) ⁽⁶⁰⁾	A study to examine long-term consequences of brain injury on health status, driving characteristics, and car accidents and to study whether driving ten years after brain injury was retrospectively related to cognitive function and on-road driving performance ten years before.	Cases were randomly sampled from patients treated for acquired brain injury (from TBI, subarachnoid hemorrhage, stroke) at a university hospital. Source of healthy matched controls not clear. All held a valid licence.	80	Not reported for N = 80	Self-report

	Continued						
	Author, Year (Country)	Description of Study	Description of Participants	Sample Size	Age in Years (Mean ± SD, Range)	Method of Evaluating Driving Safety	
Traumatic Brain Injury	Novack, 2006 (U.S.) ⁽⁶¹⁾	A study to investigate the relationship between performance on the Useful Field of View test and driving performance following TBI.	Participants were referred for evaluation by a physician to Dept. of Rehab Services, based on documented progress following TBI. All subjects had a valid driver's license. If participation in on- road test was approved by the driving evaluator, client consent was obtained.	60	Mean 33 Range 16–68	On-road testing	
	Brooke, 1992 (U.S.) ⁽⁶²⁾	A study to examine the relationship between standardized measures of cognitive function and measures of driving performance in patients with closed head injuries and in their age-matched relative or friend cohorts.	Participants were patients admitted to a regional Level I Trauma Center with a diagnosis of closed head injury 3-6 months ago. Controls were age-matched family and friends of these patients.	N = 20 Cases = 13 (TBI) Controls = 7 (a friend or relative within 5 years of the patient's age)	Mean, SD, and Range not provided. The only comment on age of participants is range of age in inclusion criteria = 18–65.	-	
Epilepsy	Crizzle, 2012 (U.S.) ⁽⁶³⁾	A study to determine which tests, from a clinical battery, are correlated with driving errors in people with epilepsy using a simulator.	Drivers with epilepsy recruited from the epilepsy monitoring unit at a university hospital.	16	Mean 44.3 ± 12.0 Range 22–68	Simulator score	

TABLE 1.

AD = Alzheimer Disease, AD-8 = Aging and Dementia -8 questionnaire, CDR = Clinical Dementia Rating scale, CNS = Central Nervous System, DMV = Department of Motor Vehicle, HD = Huntington Disease, MVA = Motor Vehicle Administration, MMSE = Mini Mental State Examination, MVC = Motor Vehicle Collision, NINCDS-ADRDA = National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association, PD = Parkinson's Disease, TBI = Traumatic Brain Injury.

Reported associat	ions of Trails B v	vith predicting driving safety (st	udies with no association shaded in gray)
Author, Year (Country)	Sample Size (in ascending order)	Association of Trails B with Predicting Driving Safety (positive or no association)	Strength of Association
Crizzle, 2012 (U.S.) ⁽⁶³⁾	16	No association	-
Fox, 1997 (Australia) ⁽⁴⁸⁾	19	No association	-
Brooke, 1992 (U.S.) ⁽⁶²⁾	20	No association	-
Szlyk, 2002 (U.S.) ⁽³⁶⁾	22	Positive	Correlation (Pearson or Spearman) $r = 0.608$, $p = .004$ for lane boundary crossing; $r = -0.571$, $p = .009$ for speed; $r = -0.563$, $p = .01$ for brake pedal pressure
Ott, 2003 (U.S.) ⁽⁵⁰⁾	27	Positive	F(1,22) test = 6.03 , $p = .02$ for relation to caregiver rating scale of driving ability
Scally, 2011 Australia) ⁽²⁶⁾	28	Positive	Pearson correlation $r = 0.61$, $p < .01$ for invalidly cued braking point in Parkinson's Disease group and $r = 0.59$, p < .01 in control group; $r = 0.58$, $p < .01$ for validly cued braking point in control group
Elkin-Frankston, 2007 (U.S.) ⁽²³⁾	29	No association (with both Trails B and Color Trails Test 2)	-
Hartman-Maier, 2008 (Israel) ⁽²⁴⁾	30	No association – with Color Trails Test 2. Does not look at Trails B.	-
Rizzo, 2001 (U.S.) ⁽⁴⁹⁾	30	Positive	Odds Ratio 13.47 for crashes (95% CI 1.19-747.68); $p = .016$
Lundqvist, 2007 (Sweden) ⁽⁵⁷⁾	30	No association	-
Alexandersen, 2009 (Norway) ⁽⁵⁶⁾	35	No association	-
Rizzo, 1997 (U.S.) ⁽⁴⁷⁾	39	Positive	Odds Ratio 30.19 for crashes (95% CI 3.8- $^{\infty}$), $p < .001$
Whelihan, 2005 (U.S.) ⁽⁵⁵⁾	46	Positive	Zero-order correlation $r = 0.46$, $p < .05$ for on-road driving evaluation
Soderstrom, 2006 (Sweden) ⁽⁵⁹⁾	54	No association	-
Petrakos, 2009 (U.S.) ⁽³¹⁾	57	No association	-
Novack, 2006 (U.S.) ⁽⁶¹⁾	60	Positive	Standardized regression coefficient = $0.29 (p < .05)$ for predictor of global driving evaluation rating and 0.03 for observer-rated Driving Assessment Scale score
Devos, 2012 (Belgium) ⁽⁵⁸⁾	60	Positive	Wilcoxon rank sum test $W = 301, p = .009$
Grace, 2005 (U.S.) ⁽⁴⁶⁾	62	Positive	F(1.34) = 13.05, p = .001 for on-road driving test
Hargrave, 2012 (U.S.) ⁽¹⁰⁾	76	Positive	Odds Ratio 1.012, $p < .05$ for on-road driving evaluation outcome
Niewoehner, 2012 (U.S.) ⁽³⁰⁾	77	Positive	p < .001 for on-road driving test; Pearson correlation coefficients done but not reported.
Lundqvist, 2008 (Sweden) ⁽⁶⁰⁾	80	No association	

TABLE 2.	
Reported associations of Trails B with predicting driving safety (studies with no association shaded in gra	ıy

		TABLE 2. Continued	
Author, Year (Country)	Sample Size (in ascending order)	Association of Trails B with Predicting Driving Safety (positive or no association)	Strength of Association
Mazer, 1998 (Canada) ⁽¹⁴⁾	84	Positive	Odds Ratio 5.96 (CI 1.83-19.42), $p < .01$ for on-road driving evaluation; Positive Predictive Value = 85.2%, Negative Predictive Value = 48.1%
Carr, 2011 (U.S.) ⁽⁵⁴⁾	85	Positive	p < .001 for on-road driving evaluation outcome
Selander, 2011 (Sweden) ⁽⁴⁴⁾	85	No association	-
Emerson, 2012 (U.S.) ⁽⁴⁰⁾	100	Positive	Hazard Ratio 1.40 (95% CI 1.06-1.84), $p < .05$ for ability to predict future crashes.
Park, 2011 (Korea) ⁽⁴³⁾	103	Positive	None provided
Bliokas, 2011 (Australia) ⁽¹⁷⁾	104	Positive	Pearson's $r = 0.28$ ($p < .01$) for number of corrective interventions performed by driving instructor during on-road test; Spearman rho = 0.32 ($p < .01$) for pass/ fail on road test
Tarawneh, 1993 (U.S.) ⁽³⁹⁾	105	Positive	Correlation coefficient -0.42, $p = .0001$ for on-road driving performance
Freund, 2008 (U.S.) ⁽³²⁾	108	Positive	F(2,76) = 9.96, $p < .001$ for driving simulator performance
Ott, 2008 (U.S.) ⁽⁵³⁾	121	Positive	Pearson's $r = 0.48$, $p < .0005$ for on-road driving evaluation score
Cushman, 1996 (U.S.) ⁽³⁸⁾	123	Positive	t = 7.10, p < .001 for on-road driving performance
Marottoli, 1998 (U.S.) ⁽¹¹⁾	125	Positive	Hazard Ratio 1.42 for self-reported events
Classen, 2008 (U.S.) ⁽¹⁶⁾	127	Positive	Odds Ratio 2.5 (95% CI 1.0-5.9) for failing on-road driving test
Betz, 2009 (U.S.) ⁽¹⁵⁾	144	No association	-
Dawson, 2009 (U.S.) ⁽⁴⁵⁾	155	No association	-
O'Connor, 2010 (U.S.) ⁽⁴²⁾	160	Positive	p < .001 for on-road driving evaluation outcome
Uc, 2005 (U.S.) ⁽⁵¹⁾	170	Positive	Spearman correlation $r = -0.45$, $p < .0001$ for Landmark and Traffic Identification Test on a driving simulator
Freund, 2008 (U.S.) ⁽³³⁾	176	No association	-
Uc, 2006 (U.S.) ⁽⁵²⁾	176	Positive	Odds Ratios for unsafe outcomes on driving simulator: 1.22 (95% CI 1.01-1.46) for crash or risky avoidance behaviour, 1.31 (95% CI 1.12-1.54) for abrupt slowing, 1.17 (95% CI 1.02-1.35) for premature stopping
Uc, 2006 (U.S.) ⁽²⁵⁾	230	Positive	Spearman correlation $r = 0.35$, $p < .01$ for Trails B-A for at-fault safety errors on driving simulator
Wood, 2008 (Australia) ⁽³⁴⁾	270	Positive	t(55.6) = -3.15, $p < .01$ for on-road driving evaluation outcome
Rozzini, 2012 (Italy) ⁽⁴¹⁾	297	Positive	Odds Ratio 2.3 (95% CI 1.06-4.9), $p < .03$ for self-reported crash

		Continued	
Author, Year (Country)	Sample Size (in ascending order)	Association of Trails B with Predicting Driving Safety (positive or no association)	Strength of Association
Kantor, 2004 (U.S.) ⁽²⁹⁾	664	Positive Reports positive association as cues needed to complete Trails B – methodology for determining "cue score" was not mentioned.	Statistical analysis for Trails B alone not provided in clear terms
Staplin, 2003 (U.S.) (original MaryPODS data) ⁽¹³⁾	1876	Positive The original data included two years of prospective crash data.	Odds Ratio 3.50, $p < .01$ for at-fault crashes; Odds Ratio 1.72, $p < .01$ for frequencies of violations
Staplin, 2003 (U.S.) (updated MaryPODS data) ⁽³⁵⁾	1876	No association This updated analysis included one additional year of driving experience.	-
Ball, 2006 (U.S.) ⁽¹²⁾	1910	Positive	Odds Ratio 1.21 (95% CI 1.01-1.44), $p = .04$ for future at-fault crashes
Stutts, 1998 (U.S.) ⁽³⁷⁾	3238	Positive	Odds Ratio 1.06 (95% CI 1.01-1.11) for crash involvement

TABLE 2.

TABLE 3. Studies reporting Trails B cut-off values

Author, Year (Country)	Reported Trails B Cut-off Value	Source of Reported Cut-off
Hargrave, 2012 (U.S.) ⁽¹⁰⁾	90 seconds	Analysis of primary driving research
Marottoli, 1998 (U.S.) ⁽¹¹⁾	133 seconds	
Ball, 2006 (U.S.) ⁽¹²⁾	147 seconds	
Staplin, 2003 (U.S.) (original MaryPODS data) ⁽¹³⁾	180 seconds	
Mazer, 1998 (Canada) ⁽¹⁴⁾	<3 errors	
Betz, 2009 (U.S.) ⁽¹⁵⁾	180 seconds	References (Wang 2003 ⁽¹⁸⁾ and Tombaugh 2004 ⁽⁶⁾) ^a
Classen, 2008 (U.S.) ⁽¹⁶⁾	3 minutes	References (Fals-Stewart 1992 ⁽²⁰⁾ and Franzen 1996 ⁽²¹⁾) ^a
Bliokas, 2011 (Australia) ⁽¹⁷⁾	\geq 292 seconds	Reference (Lezak 1983 ⁽¹⁹⁾) ^a

^aCut-offs provided in these studies are not based on primary driving research.

It is also critical that tests such as Trails B not be misused—they must be accurately interpreted in the context of a number of critical considerations, in order to ensure that they are a valid reflection of function.⁽¹⁾ In order to avoid generating false results, Trails B scores should always be interpreted in the overall clinical context when determining fitness-to-drive.⁽⁷⁾ The clinician should confirm that the Trails B results are consistent with the history provided by caregivers and other tests. Low scores must be verified as not to be due to confounding variables such as language barrier, low education, dyslexia, performance anxiety, depression, or sensory deficits, for example.

The administration of Trails B should also be standardized, as cognitive performance can be influenced by many factors. Ideally, all assessors should receive identical instructions on test administration. A practical recommendation may be that assessors receive training through continuing medical education. For a review of considerations in applying in-office tests to the assessment of fitness-to-drive, please see page 11 of http://www.canadiangeriatrics.ca/default/index.cfm/linkservid/0D194943-EF73-7DAB-77450BB92BFF239A/showMeta/0/.⁽⁷⁾ Furthermore, tests such as Trails B can be employed within a more detailed assessment process, as described in http://www.cfp.ca/content/56/11/1123.full.pdf+html?sid=6ddf379a-874a-4d6f-9c64-02c6bf939312.⁽²⁾

The evidence from the Tombaugh article⁽⁶⁾ (that the mean Trails B score for all age groups is < 3 minutes and only a small number of outliers have Trails B > 3 minutes) and the articles listing fitness-to-drive cut-offs of 3 minutes or 3 errors, ^(15,13,16,14) support the finding that the best evidence-informed cut-offs we have to date are 3 minutes or 3 errors, as described in three continuing medical education articles.^(2,7,8)

In this systematic review, none of the studies justified sample sizes via formal calculations. Eleven of the 15 studies which showed no association between Trails B and driving had small sample sizes of \leq 100. Due to the risk of type II (beta) errors (i.e., false negative results caused by inadequate sample size or insufficient power), the findings of these 11 small studies cannot be interpreted with any degree of confidence (i.e., we cannot tell if they are true negative or false negative studies). This concern may also be true for the additional three negative studies with sample sizes ranging from 144 to 176.

A limitation of the Trail Making Test is that it requires knowledge of the numbers and letters used in the English language and, thus, may not be appropriate for individuals whose primary language does not employ similar letters and numbers or those who are illiterate. One instrument that has been developed to address this concern is the Color Trails Test (CTT). The CTT is a language-free analogue of the Trails test designed to be applicable across various cultural contexts. Two studies^(23,24) (Table 2) looked at the CTT and its association with ability to predict fitness-to-drive. CTT 2 is similar to Trails B. It has two sets of 25 numbers in yellow and pink circles with instructions to connect the numbers in ascending order alternating between the two color sets. Both studies failed to show an association between CTT 2 and driving. However, it should once again be noted that both studies had small sample sizes (N = 29 and 30) and did not show sample size calculations. Therefore, as discussed above, this could have created possible false negative results in both studies.

CONCLUSION

While the evidence for Trails B cut-offs of 3 minutes or 3 errors (the '3 or 3 rule') is limited, this systematic review reveals that these represent the best evidence-informed cut-offs available to date. It is logical to assume that as the test score worsens (e.g., the time to completion and/or the numbers of errors increase), the person's fitness-to-drive also worsens

(i.e., risk of crash increases). It is, at the very least, reasonable for physicians to consider reporting findings to their Ministry of Transportation if the Trails B score is worse than 3 minutes or 3 errors, provided the test results are felt to be a valid reflection of function.

The body of evidence for Trails B cut-off scores is limited, in part, due to major methodological limitations of driving research uncovered in this study including: (1) lack of justification of sample size making the interpretation of small negative trials impossible as some negative findings may represent Type II or Beta Error (i.e., falsely negative findings due to inadequate sample size/insufficient power); and (2) the fact that most research is focused on associations but often ignores the derivation of cut-off scores, resulting in findings that are not clinically useful.

Not only is more research into Trails B cut-offs needed, but the quality of the research being done (i.e., the methodological standards) must improve. Recommendations for future driving research should therefore include:

- 1. The determination of sample size to prevent future small studies from reporting potentially falsely negative findings due to inadequate sample size/insufficient power (Type II or Beta Error). The fact that such sample size calculations are challenging does not justify their exclusion.
- 2. The determination of potential clinically useful cut-off scores using Receiver Operating Characteristic (ROC) curve analytic techniques that plot sensitivity vs. 1 specificity to permit the evaluation of the properties (e.g., sensitivity and specificity) of all potential cut-offs.
- 3. Given that there are likely no perfect cut-off scores with perfect sensitivity and specificity, techniques (e.g., Delphi techniques) that balance the risks and benefits of different cut-off scores, derived from ROC analyses, should be incorporated into driving research. Ultimately decisions regarding the best cutoffs need to be based on balancing the risks of missing cases of unsafe drivers vs. the risk of inappropriate loss of driving privileges.
- 4. Exploring the use of two cut-off scores to promote Trichotomization—see page 11 of http://www.canadian geriatrics.ca/default/index.cfm/linkservid/0D194943-EF73-7DAB-77450BB92BFF239A/showMeta/0/⁽⁷⁾ and http://onlinelibrary.wiley.com/doi/10.1111/j.1532-5415.2006.00967.x/pdf.⁽²²⁾
- 5. Exploring different scoring methods for Trails B such as Trails (B-A)^(25,26,27,28) and Trails B/A.⁽²⁹⁾ Trails (B-A) has been described as reflecting "the attention and set-switching components of Trails B independent of psychomotor speed"⁽²⁶⁾ and is often considered the standard index of set-shifting. It is also "a measure of global executive function".⁽²⁷⁾ It has been examined in various driving studies with Parkinson's Disease patients,^(25,26,27) and has been found to be a good predictor of driving

safety. It is thought that "the flexibility of the cognitive system", as tested by Trails B-A, "allows drivers to cope with dynamic traffic situations".⁽²⁸⁾ Although it is certainly a measure that is worth examining, we chose not to investigate cut-off scores for Trails (B-A) in this systematic review because current guidelines from medical associations recommend the use of Trails B only, not Trails B-A.

6. Different forms of Trails B that can overcome literacy barriers such as Color Trails.^(23,24)

In fact, we do not need to wait to add to this body of evidence. Researchers who have previously published Trails B research (or their MSc and PhD students) can immediately study the following in their existing databases: i) dichotomization via single cut-off scores (both time and number of errors), ii) trichotomization via two cut-off scores (both time and number of errors), and iii) novel scoring methods such as Trails (B - A) and Trails B/A.

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CONFLICT OF INTEREST DISCLOSURES

The authors declare that no conflicts of interest exist. Neither author has received financial support from private industry for work on the assessment of fitness-to-drive. Both authors were involved in the preparation of this manuscript.

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