

THE EFFECT OF TELFAST® 180 ON DRIVER BEHAVIOUR, DECISION-MAKING AND REACTION TIME

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ABSTRACT

The principal objective of the study was to examine the effect of Telfast® 180, an antihistamine, on driver behaviour, decision-making, and reaction time. A sample of 255 volunteers participated in the study. The sample was **randomly** divided into two groups, viz. a placebo and a Telfast group. One of the groups received Telfast and the other a placebo.

Initially all the participants were given a **standardised driving test**, as well as a **psychomotor test**. Immediately thereafter the placebo group received their placebo tablets and the Telfast group their Telfast tablets. Exactly 2,6 hours later every participant was tested again, using the same tests as before.

No statistically significant differences were found between the Placebo group and the Telfast group. No sedative effects due to Telfast® 180 were thus evident.

OPSOMMING

Die hoofdoelstelling van die studie was om die effek van Telfast® 180, 'n antihistamien, op bestuursgedrag, besluitneming en reaksietyd, te ondersoek. 'n Steekproef van 255 vrywilligers het aan die studie deelgeneem. Die steekproef is **lukraak** in twee groepe verdeel, te wete 'n plasebogroep en 'n Telfastgroep.

Om mee te begin is al die deelnemers aan 'n **gestandaardiseerde bestuurstoets**, asook 'n **psigomotoriese toets**, onderwerp. Onmiddellik daarna het die plasebogroep hul plasebotablette en die Telfastgroep hul Telfasttablette ontvang. Presies 2,6 uur later is al die deelnemers weer getoets met dieselfde toetse as voorheen.

Geen statistiese beduidende verskille is tussen die plasebogroep en die Telfastgroep gevind nie. Daar was dus geen sedatiewe effek as gevolg van Telfast® 180 nie.

Road deaths in the RSA increased tenfold from 1950 to 1998. During this period at least 300 000 people died on our roads. More than 100 000 were killed during the past ten years. In 1998 alone there were 9 068 fatalities and 36 246 serious injuries¹. From this it should be apparent that the extent of road carnage, in our country, is rapidly reaching epidemic proportions. The direct cost associated with this is astronomical: The total cost of road accidents for 1998 was estimated at R12 696,7 million and this only included costs such as loss of output of the persons killed, damage to vehicles, medical costs, legal costs, etcetera².

According to the National Rapid Response Programme, conducted by the Council for Scientific and Industrial Research (Mynhardt & De Jager, 1993), man is responsible for 81,6% of road-collisions, the vehicle for 5,6% and the road and environment for 12,8%. These sources of variation are not independent of one another, but interact with one another.

Driving a motor vehicle is a highly complex task and involves the driver as a total human being: His/her sensory abilities, motor abilities, cognitive abilities (including perceptual abilities, attention, information processing and alertness), affective disposition, emotional maturity, risk-taking behaviour, values, and attitudes towards road safety and authority. These are but a few of the psychological attributes that are of critical importance in driving a motor vehicle safely. Any substance (alcohol, drug or medicine), which affects these functions adversely, can aggravate the situation.

During 2000 the Medical Research Council examined 1 968 transport-related deaths. (These represented 42,2% of the total of 4 658 transport-related deaths.) It was found that 54% of the cases had elevated blood alcohol concentrations (BACs). Of these, 89,2% had levels greater than 0,04% (0,04g/100ml.).

Furthermore, over 50% of the drivers had elevated blood alcohol levels (mean BAC of 0,16%)³.

The debilitating effects of elevated BACs on driving performance is generally acknowledged, but the negative effects of certain medicines, notably first-generation antihistamines, are less well-known. Accordingly, the sedating effects of certain antihistamines were examined.

Weiler, Bloomfield, Woodworth, Grant, Layton, Brown, McKenzie, Baker and Watson (2000) examined the effects of fexofenadine, diphenhydramine, alcohol and a placebo on simulated driving performance. Their sample consisted of 40 licensed drivers with seasonal allergic rhinitis. Their ages varied from 25 to 44 years.

In assessing driving performance they used the Iowa Driving Simulator. All the participants had to drive 45 miles on a two-lane rural highway. The experimental drive consisted of two phases. In the first phase the participants had to follow another vehicle for 13,5 miles. Phase 2 began when the lead vehicle turned off. The participants could then drive as they 'normally would'. Towards the end of the drive the participants encountered a vehicle that unexpectedly turned in front of them. A truck with trailer occupied the oncoming lane.

The intervention consisted of the following substances, administered at weekly intervals:

- One 60 mg dose of fexofenadine
- One 50 mg dose of diphenhydramine
- Alcohol until the BAC reached 0,1%
- A placebo

For each participant the following variables were measured:

- The constancy of the following distance between the two vehicles (i.e. the correlation between the participant's vehicle velocity and the velocity of the lead vehicle).

- Steering instability (i.e. the root-mean-square deviation of the participant's car from his/her preferred position in the lane).
- The participant's reaction time to the blocking vehicle.

With regards to the participants' ability to maintain a constant following distance, it was found that (1) after taking diphenhydramine their performance was significantly poorer than after taking alcohol, fexofenadine, or a placebo and (2) after taking alcohol their following distances were significantly shorter than after taking fexofenadine.

Regarding steering instability it was found that (1) after taking fexofenadine the participants had significantly less steering instability than after taking diphenhydramine or alcohol (but not a placebo) (2) after taking alcohol the participants had the same or less steering instability than after taking diphenhydramine (3) after taking diphenhydramine the participants crossed the centre line significantly more often than after taking fexofenadine or a placebo, and (4) after taking alcohol they crossed the centre line significantly more often than after taking fexofenadine or a placebo.

With regards to the blocking vehicle, participants reacted significantly more slowly after consuming alcohol than after taking fexofenadine (2,21 seconds as against 1,95 seconds).

From the foregoing it is clear that **diphenhydramine impairs driving performance** almost to the same extent as alcohol (for BACs of approximately 0,1%).

The magnitude of the problem becomes clear if one considers that approximately 47% of Americans with allergies take first-generation-antihistamines, such as diphenhydramine (Weiler et al., 2000, p.8).

It is estimated that approximately 20% of South Africans suffer from allergic rhinitis and take some form of antihistamine (Green, Potter, Plitt, Friedman, Hockman & Davis, 1998). If one considers that 866 536 drivers were involved in motor vehicle accidents during 1998 then the magnitude of the problem is clear⁴. The question now arises: What kind of antihistamines are safe for drivers, and how conclusive is the evidence?

Vermeeren and O'Hanlon (1998) examined the effects of fexofenadine on driving performance and three psychomotor tests, namely critical tracking, choice reaction time, and sustained attention. Their sample consisted of 24 healthy volunteers. They found no evidence of driving impairment. However, there was a significant impairment of the critical tracking task for doses of 120 mg and 240 mg.

The findings of Vermeeren and O'Hanlon (1998) are most important but need to be replicated on a larger sample. A 6-way cross-over design with 24 subjects extending over five days, cannot adequately control for all relevant extraneous variables. For example, the effect of heat stress on driver vigilance should be controlled for (Wyon, Wyon & Norin, 1996). Lack of sleep is also of critical importance (Mills, Spruill, Kanne, Parkman & Zhang, 2001).

Hindmarch, Shamsi, Stanley and Fairweather (1999) studied the effects of fexofenadine, loratadine and promethazine on cognitive and psychomotor function. Their test battery included critical flicker fusion, choice reaction time and assessments of subjective sedation. Their sample consisted of 24 healthy volunteers, aged 19-58 years.

Promethazine caused a significant reduction in critical flicker fusion threshold, a significant increase in recognition reaction time and a significant increase in 'sleep-like' activity. Neither fexofenadine nor loratadine caused a significant impairment of cognitive and psychomotor function. As this study was also based on a very small sample, it should be replicated on a larger one.

Mann, Pearce, Dunn and Shakir (2000), who compared the sedating effects of loratadine, cetirizine, fexofenadine and acrivastine in a post-marketing surveillance study on 43 363 patients, found that the sedating effects of fexofenadine and loratadine were the lowest.

In the light of the foregoing evidence it appears to be safe for drivers, pilots and operators, who work with dangerous equipment, to take fexofenadine or loratadine when suffering from allergic conditions, such as rhinitis.

A brief pharmacological profile of fexofenadine (Telfast) will now be given, thereafter a South African study will be described wherein Telfast® 180 was used.

Fexofenadine HCl, the active ingredient of TELFAST®, is a non sedating antihistamine with highly selective peripheral histamine H1-receptor antagonist activity indicated for the relief of symptoms associated with seasonal allergic rhinitis and for the relief of symptoms associated with chronic idiopathic urticaria (CIU) (Medicine Control Council, 2000).

The H-1-antagonists are now commonly subdivided into two broad groups – the first generation or classical antihistamines and the second generation antihistamines with higher selectivity for H-1-receptors and **lacking the undesirable central nervous system (CNS) actions**. The second generation antihistamines are non-sedating and with little antagonist activity at other neurotransmitter receptors at therapeutic concentrations. These compounds are devoid of sedating effects due to poor CNS penetration, and possibly lowered affinities for central histaminic, cholenergic and adrenergic receptors (DeRuiter, (2001).

Fexofenadine HCl is rapidly absorbed following oral administration of tablets, with the mean t_{max} occurring at 2,6 hours post-dose (Markham & Wagstaff, 1998). The single and multiple dose pharmacokinetics of fexofenadine are linear between 40 mg and 240 mg taken daily. It exhibits an antihistaminic effect within one hour, achieves maximum effect at six hours, and lasts 24 hours. No sedative or other CNS effects have been reported for fexofenadine and studies indicate that it does not cross the blood-brain barrier (Hindmarch et al., 1999; and Markham & Wagstaff, 1998).

The most frequent adverse **symptom** reported is headache, with the incidence of fatigue and drowsiness **comparable to those found in patients receiving placebo** (Markham & Wagstaff, 1998).

Objectives of the study

The principal objective of the present study was to examine the effects of Telfast® 180, an antihistamine, on driver behaviour, decision making, and reaction time.

The following secondary objectives were also set:

- To determine the reliabilities of the various measures used.
- To examine the effects of repeated testing (test-retest) on the performance of the two treatment groups (Telfast and placebo), the two gender groups, and the three age groups.
- To ascertain whether there are gender differences in respect of the various measures used.
- To determine whether there are age differences in respect of the various measures used.

METHOD

Sample

A sample of 259 participants was randomly drawn from 600 volunteers – mostly doctors and pharmacists. However, four members were later excluded from the sample because their test records were incomplete. The final sample therefore consisted of 255 volunteers. All the participants had to be 18 years or older,

and in possession of a valid South African drivers license. There were 195 men and 60 women in the sample. Eighty participants were younger than 30 years, 94 were between 30 and 40 years, and 79 were older than 40 years. Two participants were of unknown age. A double-blind design was used in the investigation: The sample was randomly divided into two groups. One group received Telfast (N = 128), and the other group a placebo (N = 127). None of the experimenters knew who received the placebo and who received Telfast. All the participants were treated exactly the same way.

Measuring instruments

All the participants were given a standardised driving test as well as a psychomotor test.

The Driving Test

The route that the participants had to drive was carefully delineated by cones. While driving along the route the participants had to execute seven carefully planned manoeuvres. An error was committed if the wheels of the car touched any of the cones. If a wrong turn was made, a time penalty of 0,25 sec was given. The following manoeuvres were specified:

- 180° left turn
- 180° right turn
- 360° turn
- *Parking F*: The participant was required to enter a parking spot with the front of the car first and by turning 90° to the right.
- *Parking R*: The participant was required to enter a parking spot with the rear end of the car first and by turning 45° to the right.
- *Parking P*: The participant was required to enter a parallel parking spot with the rear end of the car first.
- *Slalom*: The participant was required to drive his/her car along a zigzag course, marked by cones.

Penalties were incurred if the participant grated the gears of his/her car. All the errors made and penalties incurred were added together to obtain a total score. Similarly, the time taken to complete the route, yielded a time score.

The Psychomotor Test

The psychomotor test, which is known as the Decision Reaction Test (DR2) and which forms part of the Vienna Test System developed by Schuhfried (2001), was used.

The Decision Reaction Test is computer based, and the test panel consists of:

- A yellow light
- A red light
- A large decision timer button
- A small reaction timer button
- An audible warning signal (hooter)

During the test the participants were presented with various combinations of lights and audible warnings. However, they were required to react only when a yellow light illuminated with a simultaneous audible warning. Any one of the following stimuli could be presented:

- A yellow light
- A yellow light with a simultaneous audible warning
- A red light
- A red light with a simultaneous audible warning
- An audible warning.

The test consisted of 48 stimuli of which 16 were the correct combination.

During the test participants were to keep their index finger on the large decision timer button, and if the correct stimulus was presented they were to move their finger as fast as possible to the small reaction timer button and back again to the large decision timer button.

The maximum time allowed between the presentation of the stimuli was 1,5 seconds. The test yielded four different scores, namely:

- The participants' **mean decision time** i.e. the time from the moment the stimulus was presented until they lifted their finger from the large button.
- The participants' **mean reaction time** i.e. the time from when they lifted their finger from the large button until they touched the small button.
- The number of **decision errors** the participant committed. A decision error was committed if participants reacted to an incorrect stimulus, but did not carry it through as a reaction error.
- The number of **reaction errors** participants committed. A reaction error occurred if participants reacted to an incorrect stimulus and touched the smaller button without correcting their incorrect decision.

Strictly speaking, the four scores are not experimentally independent, but are nevertheless very useful.

Procedure

During the first phase of the testing programme all the participants were given the driving test as well as the psychomotor test. Immediately after the first series of tests the placebo group received their placebo tablets and the Telfast group their Telfast tablets. Exactly 2,6 hours later every participant was tested again, using the same tests as during the first phase. Research has shown that Telfast® 180 reaches a peak concentration in the blood after 2,6 hours (Markham & Wagstaff, 1998).

Statistical analysis

As a preliminary to the main study, the reliabilities of the various measures were determined. Before analysing the data for the main study the sample was divided into two gender groups, three age groups, and two treatment groups (placebo and Telfast). To ascertain whether there were any **growth effects** due to learning, the vectors of means of the pre-test and post-test scores were compared for the two treatment groups, the two gender groups, and the three age groups. Hotelling's T^2 for dependent samples (Morrison, 1976), followed by a series of t-tests (for dependent samples), were used.

To determine the **effect of the treatment variable** on the test scores, the vectors of the pre-test and post-test means were compared for the placebo and Telfast groups. Hotelling's T^2 for independent samples, followed by a series of one-way analyses of variance, were used for this purpose. It merits mentioning that for **two** groups $F = t^2$, and $p(F) = p(t)$. A similar procedure was followed when comparing the vectors of means of the men and women.

To compare the vectors of means of the three age groups, MANOVA, followed by a series of ANOVAs and Scheffé's post hoc multiple comparisons, were used.

To compare the factor structure of the research battery for the two treatment groups, inter-group factor analysis was used (Meridith, 1964a and 1964b).

RESULTS

Reliability of measuring instruments

To begin with the reliabilities of the various measures used, were determined:

The reliability of the driving test was estimated by means of Cronbach's coefficient alpha (Scheppers, 1992, pp. 42-44), using the variance-covariance matrix of the nine error scores. The variance-covariance matrix of the first driving test is given in Table 1.

TABLE 1
VARIANCE – COVARIANCE MATRIX OF THE SUBTESTS OF THE FIRST ROAD TEST

Variables	N	1	2	3	4	5	6	7	8	9
1. 1800 Left	255	0,2476	0,0665	0,0052	0,0568	-0,0141	0,0079	0,0131	-0,0042	-0,0094
2. 1800 Right	255	0,0665	0,2565	0,0049	0,0283	0,0032	0,0051	-0,0055	-0,0009	0,0208
3. 3600 Turn	255	0,0052	0,0049	0,0115	0,0068	0,0026	0,0028	0,0066	-0,0002	0,0021
4. Parking F	255	0,0568	0,0283	0,0068	0,4378	0,0444	-0,0100	-0,0071	-0,0042	0,0145
5. Parking B	255	-0,0141	0,0032	0,0026	0,0444	0,4567	-0,0005	0,0448	-0,0047	-0,0006
6. Parking P	255	0,0079	0,0051	0,0028	-0,0100	-0,0005	0,0890	0,0066	-0,0017	0,0060
7. Slalom	255	0,0131	-0,0055	0,0066	-0,0071	0,0448	0,0066	0,1139	-0,0019	0,0081
8. Use of gears	255	-0,0042	-0,0009	-0,0002	-0,0042	-0,0047	-0,0017	-0,0019	0,0268	-0,0029
9. Route	255	-0,0094	0,0208	0,0021	0,0145	-0,0006	0,0060	0,0081	-0,0029	0,1904

Note:

$$\sum_{g=1}^k \sum_{h=1}^k r_{gh} s_g s_h \text{ (for } g \neq h) = 0,6191;$$

$$\sum_{g=1}^k s_g^2 = 1,8302$$

$$\bar{C}_{gh} = \frac{\sum_{g=1}^k \sum_{h=1}^k r_{gh} s_g s_h}{K(K-1)} = \frac{0,6191}{72} = 0,0086$$

$$s_g^2 = \sum_{g=1}^k \sum_{h=1}^k r_{gh} s_g s_h + \sum_{g=1}^k s_g^2 = 2,4493;$$

$$\alpha = \frac{K^2 \bar{C}_{gh}}{s_g^2} = \frac{81 \times 0,0086}{2,4493} = 0,284$$

TABLE 2
TEST-RETEST CORRELATIONS OF THE VARIOUS MEASURES IN RESPECT OF THE PLACEBO GROUP AND THE TELFAST GROUP

Variables	N	Placebo Group	Telfast Group	N
		Test-retest reliability	Test-retest correlation	
1. Road test: Time	127	0,843	0,825	128
2. Decision time	127	0,791	0,765	128
3. Reaction time	127	0,765	0,669	128
4. Road test: Errors	127	0,376	0,382	128
5. Decision time: Errors	127	0,465	0,496	128
6. Reaction time: Errors	127	0,389	0,237	128

A striking feature of the variance-covariance matrix is the fact that all the variances of the error scores are unusually small, suggesting a very **low reliability** for the total error score. This was confirmed by Cronbach's coefficient alpha ($\alpha = 0,284$). The reliability of the second driving test is comparably low ($\alpha = 0,345$). Both these coefficients are very low, suggesting that the error scores of the driving test are of doubtful value in the present study.

Test-retest reliabilities were computed for all the measures used in the study. Separate analyses were done for the placebo group and for the Telfast group. The results are given in Table 2.

As seen in Table 2 it is clear that the test-retest reliabilities of the **time** measures are considerably higher than for the **error** scores. The test-retest reliabilities of the time measures range from 0,765 to 0,843 for the placebo group, and from 0,669 to 0,825 for the Telfast group. The test-retest reliabilities of the error scores range from 0,237 to 0,496 for the Telfast group and from 0,376 to 0,465 for the placebo group. More weight should therefore be given to the time measures in the main study, than to the error scores.

Effects of repeated testing

The treatment groups

To compare the pre-test and post-test means of the treatment groups, the means, variances and coefficients of skewness of the various measures were computed for the placebo group and the Telfast group. The results are given in Table 3.

It is clear from Table 3 that there was a reduction in time from the pre-test to the post-test in respect of the Road Test (Time). This was true for both the placebo and the Telfast group. The reduction in time probably signifies a learning effect. However, as far as Decision Time and Reaction Time are concerned, there was an increase in time from the pre-test to the post-test. This was true for both the placebo and the Telfast group. It is probable that the participants were more cautious during the second tests.

As far as the **error scores** are concerned, there was a consistent **increase** in the number of errors committed with respect to the Road Test, Decision Time and Reaction Time. This was true for both the placebo and the Telfast groups.

A comparison of the differences in means of the pre-test and post-test scores of the treatment groups are given in Table 4.

From Table 4 it is clear that **all** the differences in means (pre-test mean minus post-test mean) of the placebo group are statistically significant. However, for the Telfast group the differences in means of Decision Time and Reaction Time are not statistically significant.

The gender groups

To compare the means of the pre-test and post-test scores of the gender groups, the means, variances and coefficients of skewness of the various measures were computed for the men and women. The results are given in Table 5.

TABLE 3
MEANS, VARIANCES AND COEFFICIENTS OF SKEWNESS OF THE PRE-TEST AND POST-TEST SCORES IN RESPECT OF THE TREATMENT GROUPS

	Placebo Group				Telfast Group			
	N	Means	Variances	Skewness	N	Means	Variances	Skewness
PRE-TEST								
1. Road test 1: Time	127	135,66	945,63	1,493	128	141,90	2352,35	2,503
2. Decision time A	127	354,79	4558,14	0,747	128	346,59	4316,39	0,213
3. Reaction time A	127	466,75	6700,35	1,129	128	467,16	5621,29	0,539
4. Road test 1: Errors	127	1,57	2,60	1,519	128	1,87	2,18	0,874
5. Decision time A: Errors	127	1,54	1,44	1,132	128	1,85	2,74	1,245
6. Reaction time A: Errors	127	0,53	0,60	1,675	128	0,54	0,60	1,637
POST-TEST								
1. Road test 2: Time	127	112,30	453,83	1,844	128	117,59	653,95	1,251
2. Decision time B	127	365,46	4869,01	0,703	128	354,05	3191,82	0,050
3. Reaction time B	127	481,27	5645,61	0,757	128	471,65	4225,79	0,194
4. Road test 2: Errors	127	2,11	3,32	1,065	128	2,20	3,12	1,051
5. Decision time B: Errors	127	2,54	3,78	1,140	128	2,93	3,74	1,191
6. Reaction time B: Errors	127	1,17	1,37	1,019	128	1,24	1,59	2,245

TABLE 4
DEPENDENT T-TESTS: COMPARISON OF MEANS OF PRE-TEST AND POST-TEST SCORES IN RESPECT OF THE TREATMENT GROUPS

Variables	Placebo Group				Telfast Group			
	\bar{X}_D	t-value	df	p	\bar{X}_D	t-value	df	p
1. Road test: Time	23,36	15,338	126	< 0,001*	24,32	8,884	127	< 0,001*
2. Decision time	-10,68	-2,707	126	0,008*	-7,46	-1,973	127	0,051
3. Reaction time	-14,52	-3,022	126	0,003*	-4,48	-0,880	127	0,381
4. Road test: Errors	-0,54	-3,152	126	0,002*	-0,34	-2,064	127	0,041*
5. Decision time: Errors	-1,00	-6,455	126	< 0,001*	-1,08	-6,714	127	< 0,001*
6. Reaction time: Errors	-0,65	-6,476	126	< 0,001*	-0,70	-6,062	127	< 0,001*

Note:

\bar{X}_D = Difference in means: pre-test mean minus post-test mean

* Statistically significant

Placebo group

Hotelling $T^2 = 316,630$

$F(6, 121) = 50,678$; $p < 0,001$

Telfast group

Hotelling $T^2 = 130,320$

$F(6, 122) = 20,865$; $p < 0,001$

From Table 5 it is clear that the pattern of means of the men and women are very similar to that of the placebo and Telfast groups, and probably for the same reasons.

A comparison of the differences in means of the pre-test and post-test scores of the men and women is given in Table 6.

From Table 6 it is clear that, for men, all the differences in means are statistically significant. However, for the women, the differences for Decision Time, Reaction Time, and Road Test (Errors), are not statistically significant. It is interesting to note that the pattern of differences in means, for men, is identical to that of the placebo group. The pattern for the women, on the other hand, is very similar to that of the Telfast group.

The age groups

To compare the means of the pre-test and post-test scores, of the various age groups, the means, variances and coefficients of skewness of the scores were computed for the participants younger than 30 years, for those between 30 and 40 years, and for those older than 40 years. The results are given in Table 7.

From Table 7 it is evident that the pattern of means of the two younger age groups (less than 30 years, and between 30 and 40

years) is very similar to that of the placebo group, whilst the pattern of the older group (40 years and more) is very similar to that of the Telfast group. This raises the issue of **representativeness** of the placebo and Telfast groups in terms of gender and age. The gender and age distributions of the placebo and Telfast groups were therefore examined. There was no difference in the gender distributions of the placebo and Telfast groups [$\chi^2(1) = 2,078$; $p = 0,149$]. Similarly, no difference was found with respect to the age distributions of the two groups [$\chi^2(2) = 0,299$; $p = 0,861$].

A comparison of the differences in means of the pre-test and post-test scores of the three age groups is given in Table 8.

From Table 8 it is clear that all the differences in means of the 30 to 40 year old group are statistically significant. For the youngest age group the difference in means of the Road Test (Errors) is statistically not significant, and for the oldest group the differences in means as regards Decision Time and Reaction Time are statistically not significant.

From the foregoing it is apparent that the measures used are sensitive enough to detect gender and age differences pertaining to the pre-test and post-test scores.

TABLE 5
MEANS, VARIANCES AND COEFFICIENTS OF SKEWNESS OF THE PRE-TEST AND POST-TEST SCORES IN RESPECT OF THE GENDER GROUPS

	Men				Women			
	N	Means	Variances	Skewness	N	Means	Variances	Skewness
Pre-test								
1. Road test 1: Time	195	129,92	1397,23	3,967	60	167,64	1424,03	0,529
2. Decision time A	195	348,56	4098,52	0,391	60	357,52	5559,41	0,634
3. Reaction time A	195	458,92	5732,03	0,842	60	493,07	6655,18	0,969
4. Road test 1: Errors	195	1,66	2,48	1,252	60	1,92	2,11	1,075
5. Decision time A: Errors	195	1,69	2,09	1,399	60	1,70	2,21	1,146
6. Reaction time A: Errors	195	0,55	0,60	1,504	60	0,47	0,59	2,193
Post-test								
1. Road test 2: Time	195	109,62	423,47	2,143	60	132,28	615,39	0,674
2. Decision time B	195	358,31	3872,52	0,633	60	364,37	4647,69	0,248
3. Reaction time B	195	469,09	4550,80	0,378	60	500,32	5531,07	0,942
4. Road test 2: Errors	195	2,15	3,45	1,108	60	2,18	2,49	0,730
5. Decision time B: Errors	195	2,74	3,31	0,928	60	2,70	5,40	1,468
6. Reaction time B: Errors	195	1,28	1,45	1,515	60	0,97	1,49	2,494

TABLE 6
DEPENDENT T-TESTS: COMPARISON OF MEANS OF PRE-TEST AND POST-TEST SCORES IN RESPECT OF THE GENDER GROUPS

Variables	Men				Women			
	\bar{X}_D	t-value	df	p	\bar{X}_D	t-value	df	p
1. Road test: Time	20,30	11,444	194	< 0,001*	35,36	12,237	59	< 0,001*
2. Decision time	-9,74	-3,140	194	0,002*	-6,85	-1,190	59	0,239
3. Reaction time	-10,17	-2,595	194	0,010*	-7,25	-0,926	59	0,358
4. Road test: Errors	-0,48	-3,408	194	0,001*	-0,27	-1,462	59	0,149
5. Decision time: Errors	-1,05	-8,645	194	< 0,001*	-1,00	-3,809	59	< 0,001*
6. Reaction time: Errors	-0,73	-8,455	194	< 0,001*	-0,50	-3,052	59	0,003*

Note:
 \bar{X}_D = Difference in means: pre-test mean minus post-test mean
 * Statistically significant

Men
 Hotelling $T^2 = 210,795$
 $F(6, 189) = 34,227$; $p < 0,001$

Women
 Hotelling $T^2 = 191,670$
 $F(6, 54) = 29,238$; $p < 0,001$

TABLE 7
MEANS, VARIANCES AND COEFFICIENTS OF SKEWNESS OF THE PRE-TEST AND POST-TEST SCORES IN RESPECT OF THE VARIOUS AGE GROUPS

Variables	<30 years			30-40 years			40+ years		
	Means	Variance	Skewness	Means	Variance	Skewness	Means	Variance	Skewness
PRE-TEST									
1. Road test 1: Time	146,24	2153,26	2,735	133,53	1529,66	2,783	136,12	1194,76	1,653
2. Decision time A	333,46	4020,18	0,709	344,81	3819,32	0,365	376,63	4682,83	0,351
3. Reaction time A	444,44	5594,45	0,623	458,79	4924,30	0,601	500,30	6672,11	1,288
4. Road test 1: Errors	1,89	2,84	0,997	1,55	1,69	1,245	1,76	2,83	1,221
5. Decision time A: Errors	1,61	2,06	1,188	1,64	2,02	1,541	1,85	2,34	1,258
6. Reaction time A: Errors	0,50	0,63	1,934	0,54	0,62	1,831	0,57	0,56	1,088
POST-TEST									
1. Road test 2: Time	117,91	574,57	1,507	110,78	530,80	1,785	115,64	477,87	1,194
2. Decision time B	346,14	3962,47	0,609	354,61	3072,24	-0,030	381,71	4603,03	0,724
3. Reaction time B	455,86	5041,41	1,022	476,54	4412,36	0,350	498,72	4673,00	0,492
4. Road test 2: Errors	2,20	3,02	0,988	2,10	3,27	1,515	2,18	3,33	0,654
5. Decision time B: Errors	2,50	4,00	0,818	2,46	2,77	1,043	3,20	3,70	1,156
6. Reaction time B: Errors	1,13	1,78	2,124	1,01	1,09	1,726	1,49	1,46	1,292
Sample size	80			94			79		

TABLE 8
DEPENDENT T-TESTS: COMPARISON OF MEANS OF PRE-TEST AND POST-TEST SCORES IN RESPECT OF THE VARIOUS AGE GROUPS

Variables	< 30 years				30-40 years				> 40 years			
	\bar{X}_D	t-value	df	p	\bar{X}_D	t-value	df	p	\bar{X}_D	t-value	df	p
1. Road test: Time	28,34	8,550	79	<0,001 *	22,75	9,791	93	<0,001 *	20,48	8,092	78	<0,001 *
2. Decision time	-12,68	-2,787	79	0,007 *	-9,80	-2,199	93	0,030 *	-5,08	-0,955	78	0,343
3. Reaction time	-11,43	-2,115	79	0,038 *	-17,76	-3,000	93	0,003 *	1,58	0,231	78	0,818
4. Road test: Errors	-0,31	-1,386	79	0,170	-0,54	-2,762	93	0,007 *	-0,42	-2,111	78	0,038 *
5. Decision time: Errors	-0,89	-4,499	79	<0,001 *	-0,82	-4,845	93	<0,001 *	-1,35	-7,009	78	<0,001 *
6. Reaction time: Errors	-0,63	-4,249	79	<0,001 *	-0,47	-4,184	93	<0,001 *	-0,92	-6,868	78	<0,001 *

Note:

\bar{X}_D = Difference in means: pre-test mean minus post-test mean

* Statistically significant

< 30 years

Hotelling T^2 = 93,456

F(6, 74) = 14,590; p < 0,001

30-40 years

Hotelling T^2 = 145,358

F(6, 88) = 22,924; p < 0,001

> 40 years

Hotelling T^2 = 140,121

F(6, 73) = 21,894; p < 0,001

TABLE 9
ANOVA: COMPARISON OF THE MEANS OF THE TREATMENT GROUPS IN RESPECT OF THE PRE-TEST AND POST-TEST MEASURES

Source	Dependent variables	Type III sum of squares	DF	Mean Square	F	p(F)
TREATMENT GROUPS: PRE-TESTS						
Placebo vs. Telfast	1. Road test 1: Time	2487,413	1,253	2487,413	1,506	0,221
	2. Decision time A	4288,015	1,253	4288,015	0,966	0,327
	3. Reaction time A	11,034	1,253	11,034	0,002	0,966
	4. Road test 1: Errors	5,747	1,253	5,747	2,408	0,122
	5. Decision time A: Errors	6,371	1,253	6,371	3,043	0,082
	6. Reaction time A: Errors	0,008	1,253	0,008	0,014	0,906
TREATMENT GROUPS: POST-TESTS						
Placebo vs. Telfast	1. Road test 2: Time	1785,459	1,253	1785,459	3,221	0,074
	2. Decision time B	8310,557	1,253	8310,557	2,064	0,152
	3. Reaction time B	5898,731	1,253	5898,731	1,196	0,275
	4. Road test 2: Errors	0,550	1,253	0,550	0,171	0,680
	5. Decision time B: Errors	9,909	1,253	9,909	2,639	0,106
	6. Reaction time B: Errors	0,303	1,253	0,303	0,205	0,651

Note:

Pre-tests

Hotelling's Trace = 0,038

F(6, 248) = 1,561; p = 0,159

Post-test

Hotelling's Trace = 0,033

F(6, 248) = 1,346; p = 0,237

Differences between treatment groups

In the light of the main objective of the study, the question arose as to whether there were any statistically significant differences between the pre-test and post-test means of the placebo group and the Telfast group.

To compare the means of the placebo group with that of the Telfast group, the data shown in Table 3 were used.

First, the vectors of the means of the placebo group and the Telfast group were compared by means of Hotelling's T^2 -test. This was done separately for the pre-test and post-test scores. Second, the means of each of the measures were compared by means of a series of one-way analyses of variance. The results are given in Table 9.

From Table 9 it is clear that the vectors of the pre-test means of the two treatment groups, do not differ statistically significantly

[F(6, 248) = 1,561; p = 0,159]. Similarly, the vectors of post-test means of the two treatment groups do not differ significantly [F(6, 248) = 1,346; p = 0,237]. None of the F-ratios, regarding the individual measures, are statistically significant. No sedative effects due to Telfast® 180 were thus evident.

Differences between men and women

To gain further evidence of the **discrimination power** of the measures used, the means of the men were compared with those of the women. These were computed separately for the pre-test and post-test scores. The data shown in Table 5 were used.

First, the vectors of means of the **men** and **women** were compared by using Hotelling's T^2 -test. This was done separately for the pre-test and post-test scores. Second, the means of each measure were compared by a series of one-way analyses of variance. The results are given in Table 10.

TABLE 10
ANOVA: COMPARISON OF THE MEANS OF THE GENDER GROUPS IN RESPECT OF THE PRE-TEST AND POST-TEST MEASURES

Source	Dependent variables	Type III sum of squares	DF	Mean Square	F	p(F)
GENDER GROUPS:		PRE-TESTS				
Men vs. women	1. Road test 1: Time	65305,70	1,253	65305,70	46,531	<0,001
	2. Decision time A	3677,40	1,253	3677,40	0,828	0,364
	3. Reaction time A	53488,95	1,253	53488,95	8,994	0,003 *
	4. Road test 1: Errors	3,11	1,253	3,11	1,296	0,256
	5. Decision time A: Errors	0,00	1,253	0,00	0,001	0,971
	6. Reaction time A: Errors	0,35	1,253	0,35	0,584	0,446
GENDER GROUPS:		POST-TESTS				
Men vs. women	1. Road test 2: Time	23557,90	1,253	23557,90	50,313	<0,001 *
	2. Decision time B	1684,40	1,253	1684,40	0,416	0,520
	3. Reaction time B	44733,49	1,253	44733,49	9,360	0,002 *
	4. Road test 2: Errors	0,05	1,253	0,05	0,017	0,896
	5. Decision time B: Errors	0,09	1,253	0,09	0,023	0,880
	6. Reaction time B: Errors	4,56	1,253	4,56	3,126	0,078

Note:
Pre-tests
 Hotelling's Trace = 0,266
 $F(6, 248) = 10,998$; $p < 0,001$
 *Statistically significant
Post-test
 Hotelling's Trace = 0,316
 $F(6, 248) = 13,053$; $p < 0,001$

TABLE 11
ANOVA: COMPARISON OF THE MEANS OF THE AGE GROUPS IN RESPECT OF THE PRE-TEST AND POST-TEST MEASURES

Source	Dependent variables	Type III sum of squares	DF	Mean Square	F	p(F)
AGE GROUPS:		PRE-TESTS				
< 30 years vs. 30-40 years vs. > 40 years	1. Road test 1: Time	7559,20	2,250	3779,60	2,330	0,099
	2. Decision time A	80108,88	2,250	40054,40	9,647	<0,001 *
	3. Reaction time A	134676,30	2,250	67338,20	11,852	<0,001 *
	4. Road test 1: Errors	4,98	2,250	2,49	1,035	0,357
	5. Decision time A: Errors	2,70	2,250	1,35	0,633	0,532
	6. Reaction time A: Errors	0,20	2,250	0,10	0,163	0,850
AGE GROUPS:		POST-TESTS				
< 30 years vs. 30-40 years vs. > 40 years	1. Road test 2: Time	2332,13	2,250	1166,07	2,208	0,112
	2. Decision time B	55300,03	2,250	27650,00	7,217	0,001 *
	3. Reaction time B	73036,03	2,250	36518,00	7,782	0,001 *
	4. Road test 2: Errors	0,53	2,250	0,27	0,083	0,921
	5. Decision time B: Errors	28,68	2,250	14,34	4,158	0,017 *
	6. Reaction time B: Errors	10,63	2,250	5,32	3,739	0,025 *

Note:
Pre-tests
 Wilks' Lambda = 0,867
 $F(12, 490) = 3,009$; $p < 0,001$
 *Statistically significant
Post-test
 Wilks' Lambda = 0,847
 $F(12, 490) = 3,537$; $p < 0,001$

From Table 10 it is clear that the vectors of pre-test means of the men and women differ significantly [$F(6, 248) = 10,998$; $p < 0,001$]. Similarly, the vectors of post-test means of the men and women differ significantly [$F(6, 248) = 13,053$; $p < 0,001$]. Furthermore, as far as the individual measures are concerned, the means of the Road Test (time) and Reaction Time, differ significantly. This is true for both the pre-test and post-test scores.

Differences between age groups

Lastly, the effect of age on the test scores was explored. The data in Table 7 were used for this purpose.

As a first step, MANOVA was used to compare the vectors of means of the three age groups. This was done separately for the pre-test and post-test scores. Thereafter, a series of one-way analyses of variance were used to compare the means of each measure. The results are given in Table 11.

From Table 11 it is clear that the vectors of pre-test means of the three age groups differ significantly [$F(12, 490) = 3,009$; $p < 0,001$]. Similarly, the vectors of post-test means of the three age groups differ significantly [$F(12, 490) = 3,537$; $p < 0,001$]. As far as the individual measures are concerned, the three age groups differed with respect to Decision Time and Reaction

TABLE 12
SCHEFFÉ'S MULTIPLE COMPARISONS: COMPARISON OF THE MEANS OF THE VARIOUS AGE GROUPS
IN RESPECT OF THE PRE-TEST AND POST-TEST MEASURES

	Means of age groups			Pairs of age groups		
	< 30 years	30-40 years	40+ years	1/2	1/3	2/3
PRE-TEST						
1. Road test 1: Time	146,24	133,53	136,12	0,118	0,287	0,915
2. Decision time A	333,46	344,81	376,63	0,513	<0,001 *	0,006*
3. Reaction time A	444,44	458,79	500,30	0,458	<0,001 *	0,002*
4. Road test 1: Errors	1,89	1,55	1,76	0,368	0,874	0,685
5. Decision time A: Errors	1,61	1,64	1,85	0,993	0,597	0,642
6. Reaction time A: Errors	0,50	0,54	0,57	0,937	0,852	0,974
POST-TEST						
1. Road test 2: Time	117,91	110,78	115,64	0,127	0,825	0,384
2. Decision time B	346,14	354,61	381,71	0,668	0,002 *	0,017*
3. Reaction time B	455,86	476,54	498,72	0,142	0,001 *	0,108
4. Road test 2: Errors	2,20	2,10	2,18	0,929	0,997	0,957
5. Decision time B: Errors	2,50	2,46	3,20	0,989	0,060	0,033*
6. Reaction time B: Errors	1,13	1,01	1,49	0,820	0,152	0,031*

Note:

* Statistically significant

Time. This applied to both the pre-test and post-test scores. Furthermore, the age groups also differed with regard to Decision Time (Errors) and Reaction Time (Errors) as far as the post-test scores are concerned.

To find out which of the age groups differed from one another in terms of the pre-test and post-test means, Scheffé's post hoc multiple comparisons technique was used. The results are given in Table 12.

From Table 12 it is clear that the youngest group's (<30 years) pre-test and post-test scores differ from those of the oldest group (40+ years) in terms of Decision Time and Reaction Time. The 30-40 year old group differs from the 40+ group in terms of Decision Time and Reaction Time, as far as the pre-test scores are concerned. For the post-test scores there are statistically significant differences in respect of Decision Time, as well as Decision time (Errors) and Reaction time (Errors). The mean Decision time and mean Reaction time of the 40+ group are consistently longer than those of the two younger groups. They also made more Decision and Reaction Time errors.

To examine the factor structure of the measures used for the placebo and Telfast groups, an inter-group factor analysis was done. For the purpose of this analysis the Road Test (Errors) was discarded because of its low reliability. The **average factor matrix** of the placebo and Telfast groups is given in Table 13. This matrix was obliquely rotated to simple structure by means of a Direct Quartimin rotation.

From Table 13 it appears that the first factor is well determined with high loadings on Decision Time A and B and Reaction Time A and B. Factor 2 is a **doublet** with high loadings on Road Tests 1 and 2 (Time). Factor 3 is well determined with high loadings on Decision Time A and B (Errors), and Reaction Time A and B (Errors).

Factor 1 can be identified as Decision Time/Reaction Time, Factor 2 relates to driving performance, and Factor 3 to Decision and Reaction errors.

The communalities of the various measures are given in the last column of Table 13. The communalities of the time measures range from 0,705 to 0,874, and the communalities of the error

scores range from 0,308 to 0,610. If the communality of a variable is taken as a lower bound for its reliability, then the reliabilities of the measures used in the present study are acceptable for research purposes (Guttman, 1957; and Mulaik, 1965, 1966).

TABLE 13
AVERAGE FACTOR MATRIX IN RESPECT OF THE PLACEBO AND
TELFAST GROUPS (DIRECT QUARTIMIN ROTATION)

Variables	Factor 1	Factor 2	Factor 3	h_j^2
1. Road test 1: Time	-0,017	0,934	-0,043	0,874
2. Road test 2: Time	0,030	0,880	0,046	0,777
3. Decision time A	0,894	-0,055	-0,030	0,803
4. Decision time B	0,896	-0,007	0,016	0,803
5. Reaction time A	0,859	-0,006	-0,001	0,738
6. Reaction time B:	0,832	0,078	0,007	0,705
7. Decision time A: Errors	-0,091	-0,068	0,602	0,375
8. Decision time B: Errors	-0,054	0,100	0,773	0,610
9. Reaction time A: Errors	0,099	-0,084	0,540	0,308
10. Reaction time B: Errors	0,019	0,092	0,653	0,435

The factor variances of the placebo and Telfast groups are given in Table 14.

TABLE 14
FACTOR VARIANCES IN RESPECT OF THE
PLACEBO AND TELFAST GROUPS

Groups	Factor 1	Factor 2	Factor 3
Placebo group	1,14	0,69	0,98
Telfast group	0,86	1,31	1,02
Total group	2,00	2,00	2,00

From Table 14 it appears that the variance of Factor 1 is slightly higher for the placebo group than for the Telfast group. This implies that Factor 1 is slightly better developed for the placebo group than for the Telfast group. The opposite is true for Factor 2. Here the variance of the Telfast group is considerably larger than that of the placebo group.

Factor 2 is therefore better developed for the Telfast group than the placebo group. The variances of Factor 3 are virtually the same for the two groups.

The intercorrelations of the factors of the placebo and Telfast groups are given in Table 15.

TABLE 15
INTERCORRELATIONS OF FACTORS IN RESPECT
OF THE PLACEBO AND TELFAST GROUPS

	Placebo group			Telfast group		
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3
Factor 1	1,00	0,02	0,00	1,00	0,01	-0,06
Factor 2	0,02	1,00	0,00	0,01	1,00	0,04
Factor 3	0,00	0,00	1,00	-0,06	0,04	1,00

From Table 15 it is clear that the factor structures of the two groups are similar. Furthermore, they are strictly **orthogonal**, despite the fact that an oblique rotation was used. There was therefore no indication of a regression towards an undifferentiated state due to the ingestion of Telfast® 180.

DISCUSSION OF RESULTS

As far as the secondary objectives of the study are concerned it was found that the Driving Test as well as the Decision-making and Reaction Time Test yielded acceptable reliabilities, particularly as far as the time scores were concerned. All the measures were sensitive enough to pick-up test-retest effects, and to differentiate between the gender and age groups.

With regard to the major objectives of the study it was found that there were no differences on any of the measures between the Telfast and placebo groups.

As regards the structure of the measures used, the factor variances of the two treatment groups are very similar: The first factor is slightly better developed for the placebo group than the Telfast group. Factor 2 is considerably better developed for the Telfast group than the placebo group, and Factor 3 is equally well developed for both groups. The factor intercorrelations are virtually the same for the two groups, and indicate that the factors are essentially **orthogonal** to one another. The factor structures of the two groups are therefore essentially the same. The fact that the two intercorrelation matrices are essentially **orthogonal** implies that there was no regression towards an **undifferentiated state** due to the ingestion of Telfast® 180. There is therefore no evidence that Telfast® had a **sedating effect** on the participants who completed the Driving Test and the Psychomotor Tests.

The findings of the present study are in keeping with the pharmacological profile of Telfast: Fexofenadine HCl, the active ingredient of Telfast, is a **non sedating antihistamine** with highly **selective** peripheral histamine H1-receptor antagonist activity (Hindmarch et al., 1999; and Markham & Wagstaff, 1998). It is claimed to be free of the negative effects of first generation antihistamines.

The results of the present study are supported by the findings of Weiler et al. (2000) who found that fexofenadine did not affect driving performance to the same extent as diphenhydramine or alcohol.

The findings of the present study also support those of Vermeeren and O'Hanlon (1998). They found no evidence of driving performance impairment in respect of fexofenadine. Also Hindmarch et al. (1999) found that neither fexofenadine nor loratadine caused a significant impairment of cognitive and psychomotor function.

Mann et al. (2000) found that the sedating effects of fexofenadine and loratadine were the lowest compared to cetirizine and acrivastine.

The findings of the present study are very promising indeed. No indications of driving performance impairment, associated with the use of Telfast® 180, were found. However, further research should investigate whether the continuous use of Telfast® 180 has any negative effects.

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Road safety statistics:

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