Clinical trial results:
Multi-center, prospective, controlled, randomized, single-blinded study to evaluate the efficacy of vibrotactile neuro-feedback additionally to intake of Ginkgo biloba special extract EGb 761® for the treament of presby vertigo.

Summary

EudraCT number	2014-000303-28
Trial protocol	DE
Global end of trial date	19 June 2018

Results information

Result version number	v1 (current)
This version publication date	30 June 2019
First version publication date	30 June 2019

Trial information

Trial identification

Sponsor protocol code	MW029

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Dr. Willmar Schwabe GmbH & Co. KG
Sponsor organisation address	Willmar-Schwabe Str. 4, Karlsruhe, Germany, 76227
Public contact	Medical Affairs, Dr. Willmar Schwabe GmbH & Co. KG, +49 7243106577, MW029@schwabe.de
Scientific contact	Medical Affairs, Dr. Willmar Schwabe GmbH & Co. KG, +49 7243106577, MW029@schwabe.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	29 May 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 June 2018
Global end of trial reached?	Yes
Global end of trial date	19 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Proof of the efficacy of vibrotactile neurofeedback using VertiGuard® RT in addition to EGb 761® for presbyvertigo

Protection of trial subjects:

Safety monitoring (adverse events [AEs], serious adverse events [SAEs], adverse drug reactions [ADRs]), assessment of laboratory data (blood chemistry, hematology), physical examination, ECG and vital signs.

Background therapy:

None

Evidence for comparator:

n/a

Actual start date of recruitment	15 December 2014
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	7
From 65 to 84 years	108

85 years and over	5

Subject disposition

Recruitment

Recruitment details:

120 subjects were enrolled and randomized. The duration of the recruitment phase was about three years. First subject was screened on 07-Jan-2015, the last patient completed on 19-Jun-2018.

Pre-assignment

Screening details:

Suitable subjects were selected by the investigator according to the eligibility criteria specified in the protocol.

Pre-assignment period milestones

Number of subjects started	190[1]
Number of subjects completed	120

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Screening failure: 70

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: 190 patients have been screened. 70 patients were not eligible for participation as they did not fullfil eligibility criteria. 120 patients were actually enrolled and randomized.

Period 1

Period 1 title	Randomization
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Neither investigators nor patients were blinded in respect to the study treatment EGb 761®. Patients were blinded in respect to the mode of vibrotactile feedback VertiGuard® RT (normal vs. insensitive). Blinding of investigators in respect to the mode of vibrotactile feedback VertiGuard® RT was technically not feasible.

Arms

Are arms mutually exclusive?	Yes
Arm title	EGb 761® + normal vibrotactile feedback

Arm description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and normal individually adapted balance training with vibrotactile feedback using VertiGuard® RT for two weeks.

Arm type	Experimental
Investigational medicinal product name	EGb 761®
Investigational medicinal product code	
Other name	Tebonin® spezial 80 mg
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

80 mg, twice daily, p.o., film-coated tablet

Arm title	EGb 761® + insensitive vibrotactile feedback

Arm description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and balance training with insensitive "sham" vibrotactile feedback using VertiGuard® RT for two weeks.

Arm type	Experimental

Investigational medicinal product name	EGb 761®
Investigational medicinal product code	
Other name	Tebonin® spezial 80 mg
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

80 mg, twice daily, p.o., film-coated tablet

Number of subjects in period 1	EGb 761® + normal vibrotactile feedback	EGb 761® + insensitive vibrotactile feedback
Started	59	61
Randomized	59	61
Completed	59	61

Period 2

Period 2 title	Baseline
Is this the baseline period?	Yes[2]
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Neither investigators nor patients were blinded in respect to the study treatment EGb 761®. Patients were blinded in respect to the mode of vibrotactile feedback VertiGuard® RT (normal vs. insensitive). Blinding of investigators in respect to the mode of vibrotactile feedback VertiGuard® RT was technically not feasible.

Arms

Are arms mutually exclusive?	Yes
Arm title	EGb 761® + normal vibrotactile feedback

Arm description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and normal individually adapted balance training with vibrotactile feedback using VertiGuard® RT for two weeks.

Arm type	Experimental
Investigational medicinal product name	EGb 761®
Investigational medicinal product code	
Other name	Tebonin® spezial 80 mg
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

80 mg, twice daily, p.o., film-coated tablet

Arm title	EGb 761® + insensitive vibrotactile feedback

Arm description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and balance training with insensitive "sham" vibrotactile feedback using VertiGuard® RT for two weeks.

Arm type	Experimental
Investigational medicinal product name	EGb 761®
Investigational medicinal product code	
Other name	Tebonin® spezial 80 mg
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

80 mg, twice daily, p.o., film-coated tablet

Notes:

[2] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Baseline assessments were performed after randomization (period 1).

Number of subjects in period 2	EGb 761® + normal vibrotactile feedback	EGb 761® + insensitive vibrotactile feedback
Started	59	61
Completed	59	61

Period 3

Period 3 title	Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Neither investigators nor patients were blinded in respect to the study treatment EGb 761®. Patients were blinded in respect to the mode of vibrotactile feedback VertiGuard® RT (normal vs. insensitive). Blinding of investigators in respect to the mode of vibrotactile feedback VertiGuard® RT was technically not feasible.

Arms

Are arms mutually exclusive?	Yes
Arm title	EGb 761® + normal vibrotactile feedback

Arm description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and normal individually adapted balance training with vibrotactile feedback using VertiGuard® RT for two weeks.

Arm type	Experimental
Investigational medicinal product name	EGb 761®
Investigational medicinal product code	
Other name	Tebonin® spezial 80 mg
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

80 mg, twice daily, p.o., film-coated tablet

Arm title	EGb 761® + insensitive vibrotactile feedback

Arm description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and balance training with insensitive "sham" vibrotactile feedback using VertiGuard® RT for two weeks.

Arm type	Experimental
Investigational medicinal product name	EGb 761®
Investigational medicinal product code	
Other name	Tebonin® spezial 80 mg
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

80 mg, twice daily, p.o., film-coated tablet

Number of subjects in period 3	EGb 761® + normal vibrotactile feedback	EGb 761® + insensitive vibrotactile feedback
Started	59	61
Completed	51	56
Not completed	8	5
Eligibility criteria not met	3	-
Consent withdrawn by subject	1	1
Adverse event, non-fatal	4	4

Baseline characteristics

Reporting groups

Reporting group title	EGb 761® + normal vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and normal individually adapted balance training with vibrotactile feedback using VertiGuard® RT for two weeks.

Reporting group title	EGb 761® + insensitive vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and balance training with insensitive "sham" vibrotactile feedback using VertiGuard® RT for two weeks.

Reporting group values	EGb 761® + normal vibrotactile feedback	EGb 761® + insensitive vibrotactile feedback	Total
Number of subjects	59	61	120
Age categorical Units: Subjects			
Adults (18-64 years)	3	4	7
From 65-84 years	54	54	108
85 years and over	2	3	5
Age continuous Units: years			
arithmetic mean	74.1	74.3	
standard deviation	± 5.48	± 6.44	-
Gender categorical Units: Subjects			
Female	42	39	81
Male	17	22	39
Race Units: Subjects			
Caucasian	59	61	120

Subject analysis sets

Subject analysis set title	FAS - Arm A (EGb 761® + normal vibrotactile feedback)
Subject analysis set type	Full analysis

Subject analysis set description:

Full Analysis Set of treatment arm A (EGb 761® + normal vibrotactile feedback).
The FAS includes all randomized patients that received at least one dose of the study medication and who performed at least one day of balance training and for which at least one post-baseline measurement of the primary variable was available.

Subject analysis set title	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Subject analysis set type	Full analysis

Subject analysis set description:

Full Analysis Set of treatment arm B (EGb 761® + insensitve vibrotactile feedback).
The FAS includes all randomized patients that received at least one dose of the study medication and who performed at least one day of balance training and for which at least one post-baseline measurement of the primary variable was available.

Subject analysis set title	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

NCAS: Analysis Set Under Normal Conditions | NCAS of treatment arm A (EGb 761® + normal vibrotactile feedback).
In the NCAS data were excluded that were due to handling errors/incorrect use of the medical device (VertiGuard® RT).
Patients from the FAS were included in the NCAS with exception of patients from Center 2 (conflicting information about sensitivity during training) and from Center 3 (exercises performed with systematically decreasing instead of individually adapted increasing sensitivity).

Subject analysis set title	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

NCAS: Analysis Set Under Normal Conditions | NCAS of treatment arm B (EGb 761® + insensitive vibrotactile feedback).
In the NCAS data were excluded that were due to handling errors/incorrect use of the medical device (VertiGuard® RT).
Patients from the FAS were included in the NCAS with exception of patients from Center 2 (conflicting information about sensitivity during training) and from Center 3 (exercises performed with systematically decreasing instead of individually adapted increasing sensitivity).

Subject analysis set title	AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

AAS: Additional analysis set | AAS of treatment arm A (EGb 761® + normal vibrotactile feedback).
In the AAS data from Center 2 were excluded. Patients from the FAS were included in the AAS with exception of patients from Center 2 (conflicting information about sensitivity during training).

Subject analysis set title	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

AAS: Additional analysis set | AAS of treatment arm B (EGb 761® + insensitive vibrotactile feedback).
In the AAS data from Center 2 were excluded. Patients from the FAS were included in the AAS with exception of patients from Center 2 (conflicting information about sensitivity during training).

Reporting group values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects	53	56	29
Age categorical Units: Subjects			
Adults (18-64 years)	3	4	0
From 65-84 years	48	49	28
85 years and over	2	3	1
Age continuous Units: years			
arithmetic mean	74.0	74.0	74.5
standard deviation	± 5.61	± 6.60	± 4.69
Gender categorical Units: Subjects			
Female	39	34	22
Male	14	22	7
Race Units: Subjects			
Caucasian	53	56	29

Reporting group values	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects	29	42	43

Age categorical Units: Subjects			
Adults (18-64 years)	4		
From 65-84 years	24		
85 years and over	1		
Age continuous Units: years			
arithmetic mean	73.3		
standard deviation	± 6.80	±	±
Gender categorical Units: Subjects			
Female	20		
Male	9		
Race Units: Subjects			
Caucasian	29		

End points

End points reporting groups

Reporting group title	EGb 761® + normal vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and normal individually adapted balance training with vibrotactile feedback using VertiGuard® RT for two weeks.

Reporting group title	EGb 761® + insensitive vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and balance training with insensitive "sham" vibrotactile feedback using VertiGuard® RT for two weeks.

Reporting group title	EGb 761® + normal vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and normal individually adapted balance training with vibrotactile feedback using VertiGuard® RT for two weeks.

Reporting group title	EGb 761® + insensitive vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and balance training with insensitive "sham" vibrotactile feedback using VertiGuard® RT for two weeks.

Reporting group title	EGb 761® + normal vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and normal individually adapted balance training with vibrotactile feedback using VertiGuard® RT for two weeks.

Reporting group title	EGb 761® + insensitive vibrotactile feedback

Reporting group description:

Patients receive EGb 761® 80 mg p.o. twice daily for 12 weeks and balance training with insensitive "sham" vibrotactile feedback using VertiGuard® RT for two weeks.

Subject analysis set title	FAS - Arm A (EGb 761® + normal vibrotactile feedback)
Subject analysis set type	Full analysis

Subject analysis set description:

Full Analysis Set of treatment arm A (EGb 761® + normal vibrotactile feedback).
The FAS includes all randomized patients that received at least one dose of the study medication and who performed at least one day of balance training and for which at least one post-baseline measurement of the primary variable was available.

Subject analysis set title	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Subject analysis set type	Full analysis

Subject analysis set description:

Full Analysis Set of treatment arm B (EGb 761® + insensitve vibrotactile feedback).
The FAS includes all randomized patients that received at least one dose of the study medication and who performed at least one day of balance training and for which at least one post-baseline measurement of the primary variable was available.

Subject analysis set title	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

NCAS: Analysis Set Under Normal Conditions | NCAS of treatment arm A (EGb 761® + normal vibrotactile feedback).
In the NCAS data were excluded that were due to handling errors/incorrect use of the medical device (VertiGuard® RT).
Patients from the FAS were included in the NCAS with exception of patients from Center 2 (conflicting information about sensitivity during training) and from Center 3 (exercises performed with systematically decreasing instead of individually adapted increasing sensitivity).

Subject analysis set title	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

NCAS: Analysis Set Under Normal Conditions | NCAS of treatment arm B (EGb 761® + insensitive vibrotactile feedback).

In the NCAS data were excluded that were due to handling errors/incorrect use of the medical device (VertiGuard® RT).
Patients from the FAS were included in the NCAS with exception of patients from Center 2 (conflicting information about sensitivity during training) and from Center 3 (exercises performed with systematically decreasing instead of individually adapted increasing sensitivity).

Subject analysis set title	AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

AAS: Additional analysis set | AAS of treatment arm A (EGb 761® + normal vibrotactile feedback).
In the AAS data from Center 2 were excluded. Patients from the FAS were included in the AAS with exception of patients from Center 2 (conflicting information about sensitivity during training).

Subject analysis set title	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Subject analysis set type	Modified intention-to-treat

Subject analysis set description:

AAS: Additional analysis set | AAS of treatment arm B (EGb 761® + insensitive vibrotactile feedback).
In the AAS data from Center 2 were excluded. Patients from the FAS were included in the AAS with exception of patients from Center 2 (conflicting information about sensitivity during training).

Primary: Primary Endpoint - Change of tendency of falling | FAS

End point title	Primary Endpoint - Change of tendency of falling	FAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test) | Analysis by MMRM.

End point type	Primary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days)

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	52[1]	55[2]		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-6.1 (± 8.54)	-4.0 (± 10.31)		

Notes:

[1] - Data for one patient missing.

[2] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[3]
P-value	= 0.1092
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.4468

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.4
upper limit	0.6

Notes:

[3] - The analyses included the fixed, categorical effects of treatment, investigative site, visit, and treatment-by-visit interaction as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=317.

Statistical analysis title	Post hoc power calculation
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Post-hoc
Analysis type	other[4]
P-value	= 0.05
Method	Post hoc power calculation

Notes:

[4] - A post-hoc power calculation based on standard deviation 9.96, correlation between outcome and baseline covariate 0.593, clinical, treatment effect -2.44688, alpha = 0.05 and N=109 resulted in 35% power.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - CCA

Statistical analysis description:

Sensitivity Analysis (Complete Case Analysis) - Regarding only patients in the FAS with complete data in respect to the primary data.

Comparison groups	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback) v FAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[5]
P-value	= 0.1116
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.4567
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	0.6

Notes:

[5] - MMRM analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=107.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - LOCF

Statistical analysis description:

Sensitivity Analysis (Last-Observation-Carried-Forward; LOCF) - Missing values for patients in the FAS imputed by LOCF method.

Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)

Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[6]
P-value	= 0.1751
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.0901
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	0.9

Notes:

[6] - MMRM analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=109.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - MI

Statistical analysis description:

Sensitivity Analysis (Multiple Imputation, MI) - Missing values for patients in the FAS imputed by the MI method.

Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[7]
P-value	= 0.1105
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.4725
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.5
upper limit	0.6

Notes:

[7] - MMRM analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=109.

Primary: Primary Endpoint - Change of tendency of falling | NCAS

End point title	Primary Endpoint - Change of tendency of falling	NCAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test) | NCAS: Analysis Set Under Normal Conditions - Rejecting data from incorrect use of the medical device (VertiGuard® RT).
Analysis by MMRM.

End point type	Primary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days)

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-7.1 (± 4.74)	-5.6 (± 8.62)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[8]
P-value	= 0.3593
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.5524
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	1.8

Notes:

[8] - The analyses included the fixed, categorical effects of treatment, investigative site, visit, and treatment-by-visit interaction as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - CCA
Statistical analysis description:	
Sensitivity Analysis (Complete Case Analysis) - Regarding only patients in the FAS with complete data in respect to the primary data.	
Comparison groups	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[9]
P-value	= 0.363
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.5472
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	1.8

Notes:

[9] - MMRM Analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=58.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - LOCF

Statistical analysis description:

Sensitivity Analysis (Last-Observation-Carried-Forward; LOCF) - Missing values for patients in the FAS imputed by LOCF method.

Comparison groups	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[10]
P-value	= 0.363
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.5472
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	1.8

Notes:

[10] - MMRM Analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=58.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - MI

Statistical analysis description:

Sensitivity Analysis (Multiple Imputation, MI) - Missing values for patients in the FAS imputed by the MI method.

Comparison groups	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[11]
P-value	= 0.363
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.5472
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	1.8

Notes:

[11] - MMRM Analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=58.

Primary: Primary Endpoint - Change of tendency of falling | AAS

End point title	Primary Endpoint - Change of tendency of falling	AAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test) | AAS: Additional Analysis Set | Analysis by MMRM.

End point type	Primary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days)

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-7.1 (± 8.52)	-4.7 (± 8.33)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[12]
P-value	= 0.0691
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.8918
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	0.2

Notes:

[12] - The analyses included the fixed, categorical effects of treatment, investigative site, visit, and treatment-by-visit interaction as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - CCA

Statistical analysis description:

Sensitivity Analysis (Complete Case Analysis) - Regarding only patients in the analysis set with complete data in respect to the primary data.

Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[13]
P-value	= 0.0713
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.8762
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	0.3

Notes:

[13] - MMRM analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=85.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - LOCF

Statistical analysis description:

Sensitivity Analysis (Last-Observation-Carried-Forward; LOCF) - Missing values for patients in the analysis set imputed by LOCF method.

Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[14]
P-value	= 0.0713
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.8762
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	0.3

Notes:

[14] - MMRM analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=85.

Statistical analysis title	Mixed Model Repeated Measures (MMRM) - MI

Statistical analysis description:

Sensitivity Analysis (Multiple Imputation, MI) - Missing values for patients in the analysis set imputed by the MI method.

Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[15]
P-value	= 0.0713
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.8762

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6
upper limit	0.3

Notes:

[15] - MMRM analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=85.

Secondary: Sec. Endpoint 1: Change of tendency of falling after 4 weeks |FAS

End point title	Sec. Endpoint 1: Change of tendency of falling after 4 weeks |FAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test).
Analysis by MMRM.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days)

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	52[16]	55[17]		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-0.8 (± 9.26)	-0.7 (± 7.70)		

Notes:

[16] - Data for one patient missing.

[17] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[18]
P-value	= 0.9846
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.02904
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3
upper limit	3

Notes:

[18] - The analyses included the fixed, categorical effects of treatment, investigative site, visit, and treatment-by-visit interaction as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=317.

Secondary: Sec. Endpoint 1: Change of tendency of falling after 12 weeks |FAS

End point title	Sec. Endpoint 1: Change of tendency of falling after 12 weeks |FAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test).
Analysis by MMRM.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days)

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	50[19]	53[20]		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-6.7 (± 8.79)	-4.5 (± 10.30)		

Notes:

[19] - Data for three patients missing.

[20] - Data for three patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	other[21]
P-value	= 0.1179
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.5133
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.7
upper limit	0.6

Notes:

[21] - The analyses included the fixed, categorical effects of treatment, investigative site, visit, and treatment-by-visit interaction as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction.
Note: The number of subjects included in the analysis was set automatically by the database. The actual

number of values contributing to this statistics is n=317.

Secondary: Sec. Endpoint 1: Change of tendency of falling after 4 weeks | NCAS	
End point title	Sec. Endpoint 1: Change of tendency of falling after 4 weeks | NCAS
End point description:	
Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test). Analysis by MMRM.	
End point type	Secondary
End point timeframe:	
After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).	

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-1.9 (± 6.12)	-1.5 (± 6.79)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[22]
P-value	= 0.7962
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.4027
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	2.7

Notes:

[22] - The analyses included the fixed, categorical effects of treatment, investigative site, visit, and treatment-by-visit interaction as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 1: Change of tendency of falling after 12 weeks |NCAS

End point title	Sec. Endpoint 1: Change of tendency of falling after 12 weeks |NCAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test).
Analysis by MMRM.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days)

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[23]	29		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-6.7 (± 6.19)	-5.0 (± 8.67)		

Notes:

[23] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[24]
P-value	= 0.3509
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.7855
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.6
upper limit	2

Notes:

[24] - The analyses included the fixed, categorical effects of treatment, investigative site, visit, and treatment-by-visit interaction as well as the continuous, fixed covariates of baseline score and baseline score-by-visit interaction.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 1: Proportion of patients with pathological balance disorders |FAS

End point title	Sec. Endpoint 1: Proportion of patients with pathological balance disorders |FAS

End point description:

Proportion of patients with pathological balance disorders assessed by 14 gSBDT-excercises.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Proportion of patients (%)				
Screening - Exercise 1	55	55		
Screening - Exercise 2	55	57		
Screening - Exercise 3	55	50		
Screening - Exercise 4	64	68		
Screening - Exercise 5	57	54		
Screening - Exercise 6	77	73		
Screening - Exercise 7	45	54		
Screening - Exercise 8	77	84		
Screening - Exercise 9	66	79		
Screening - Exercise 10	68	75		
Screening - Exercise 11	81	84		
Screening - Exercise 12	62	66		
Screening - Exercise 13	43	34		
Screening - Exercise 14	57	43		
Baseline - Exercise 1	64	70		
Baseline - Exercise 2	57	64		
Baseline - Exercise 3	66	64		
Baseline - Exercise 4	72	73		
Baseline - Exercise 5	57	59		
Baseline - Exercise 6	74	80		
Baseline - Exercise 7	60	59		
Baseline - Exercise 8	81	79		
Baseline - Exercise 9	66	64		
Baseline - Exercise 10	74	71		
Baseline - Exercise 11	76	80		
Baseline - Exercise 12	62	73		
Baseline - Exercise 13	47	38		
Baseline - Exercise 14	59	55		
Week 4 - Exercise 1	53	57		
Week 4 - Exercise 2	53	52		
Week 4 - Exercise 3	59	55		
Week 4 - Exercise 4	76	70		
Week 4 - Exercise 5	53	54		
Week 4 - Exercise 6	74	82		
Week 4 - Exercise 7	51	64		
Week 4 - Exercise 8	70	82		
Week 4 - Exercise 9	70	80		

Week 4 - Exercise 10	76	79		
Week 4 - Exercise 11	81	84		
Week 4 - Exercise 12	57	70		
Week 4 - Exercise 13	42	43		
Week 4 - Exercise 14	55	57		
Week 6 - Exercise 1	47	55		
Week 6 - Exercise 2	47	52		
Week 6 - Exercise 3	49	46		
Week 6 - Exercise 4	68	79		
Week 6 - Exercise 5	34	36		
Week 6 - Exercise 6	49	63		
Week 6 - Exercise 7	60	61		
Week 6 - Exercise 8	72	75		
Week 6 - Exercise 9	70	66		
Week 6 - Exercise 10	74	77		
Week 6 - Exercise 11	72	73		
Week 6 - Exercise 12	62	73		
Week 6 - Exercise 13	53	55		
Week 6 - Exercise 14	53	52		
Week 12 - Exercise 1	47	52		
Week 12 - Exercise 2	49	54		
Week 12 - Exercise 3	43	48		
Week 12 - Exercise 4	66	73		
Week 12 - Exercise 5	34	36		
Week 12 - Exercise 6	49	55		
Week 12 - Exercise 7	62	57		
Week 12 - Exercise 8	66	71		
Week 12 - Exercise 9	62	77		
Week 12 - Exercise 10	64	75		
Week 12 - Exercise 11	72	75		
Week 12 - Exercise 12	60	68		
Week 12 - Exercise 13	43	52		
Week 12 - Exercise 14	42	63		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 1: Proportion of patients with >50% risk of falling | FAS

End point title	Sec. Endpoint 1: Proportion of patients with >50% risk of falling | FAS

End point description:

Proportion of patients with >50% risk of falling based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Proportion of patients (%)				
Screening	63	65		
Baseline - Day 0	67	63		
Week 4	56	66		
Week 6	39	56		
Week 12	38	55		

Statistical analyses

Statistical analysis title	Chi-square Test - Screening
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[25]
P-value	= 0.8254
Method	Chi-squared

Notes:

[25] - Chi-square Test - Screening (N=105: Arm A: 51 | Arm B: 54)

Statistical analysis title	Chi-square Test - Baseline
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[26]
P-value	= 0.6528
Method	Chi-squared

Notes:

[26] - Chi-square Test - Baseline (N=107: Arm A: 51 | Arm B: 56)

Statistical analysis title	Chi-square Test - Week 6
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[27]
P-value	= 0.0639
Method	Chi-squared

Notes:

[27] - Chi-square Test - Week 6 (N=107: Arm A: 52 | Arm B: 55)

Statistical analysis title	Chi-square Test - Week 12
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[28]
P-value	= 0.0892
Method	Chi-squared

Notes:

[28] - Chi-square Test - Week 6 (N=103: Arm A: 50 | Arm B: 55)

Secondary: Sec. Endpoint 1: Proportion of patients with >40% risk of falling | FAS

End point title	Sec. Endpoint 1: Proportion of patients with >40% risk of falling | FAS

End point description:

Proportion of patients with >40% risk of falling based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Proportion of patients (%)				
Screening	100	100		
Baseline - Day 0	100	96		
Week 4	94	98		
Week 6	83	89		
Week 12	84	91		

Statistical analyses

Statistical analysis title	Chi square test - Baseline
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[29]
P-value	= 0.1731
Method	Chi-squared

Notes:

[29] - Chi square test - Baseline (N=107: Arm A:51 | Arm B:56)

Statistical analysis title	Chi square test - Week 4
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[30]
P-value	= 0.2816
Method	Chi-squared

Notes:

[30] - Chi square test - Week 4 (N=107: Arm A:52 | Arm B:55)

Statistical analysis title	Chi square test - Week 6
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[31]
P-value	= 0.3407
Method	Chi-squared

Notes:

[31] - Chi square test - Week 6 (N=107: Arm A:52 | Arm B:55)

Statistical analysis title	Chi square test - Week 12
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[32]
P-value	= 0.3159
Method	Chi-squared

Notes:

[32] - Chi square test - Week 12 (N=103: Arm A:50 | Arm B:53)

Secondary: Sec. Endpoint 1: Average Trunk Sway in Roll-Direction| FAS

End point title	Sec. Endpoint 1: Average Trunk Sway in Roll-Direction| FAS

End point description:

Mean dorsoventral imbalance of patients based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Absolute values (°/sec)				
arithmetic mean (standard deviation)				
Screening	5.6 (± 1.03)	5.6 (± 1.26)		
Baseline - Day 0	5.6 (± 0.93)	5.6 (± 1.50)		
Week 4	5.5 (± 1.23)	5.6 (± 1.35)		
Week 6	5.3 (± 1.27)	5.9 (± 1.62)		
Week 12	5.3 (± 1.12)	5.7 (± 1.58)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 1: Average Trunk Sway in Pitch-Direction | FAS

End point title	Sec. Endpoint 1: Average Trunk Sway in Pitch-Direction | FAS

End point description:

Mean lateral imbalance of patients based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Absolute values (°/sec.)				
arithmetic mean (standard deviation)				
Screening	4.8 (± 1.11)	4.7 (± 0.91)		
Baseline - Day 0	4.9 (± 1.24)	4.9 (± 1.05)		
Week 4	4.9 (± 1.32)	4.9 (± 1.14)		
Week 6	4.7 (± 0.98)	4.9 (± 1.10)		
Week 12	4.7 (± 1.07)	5.0 (± 1.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 1: Proportion of patients with pathological balance disorders |NCAS

End point title	Sec. Endpoint 1: Proportion of patients with pathological balance disorders |NCAS

End point description:

Proportion of patients in the NCAS with pathological balance disorders assessed by 14 gSBDT-excercises.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Proportion of patients (%)				
Screening - Exercise 1	45	45		
Screening - Exercise 2	45	48		
Screening - Exercise 3	35	28		
Screening - Exercise 4	59	66		
Screening - Exercise 5	52	55		
Screening - Exercise 6	72	66		
Screening - Exercise 7	48	52		
Screening - Exercise 8	90	93		
Screening - Exercise 9	79	83		
Screening - Exercise 10	72	97		
Screening - Exercise 11	86	93		
Screening - Exercise 12	72	83		
Screening - Exercise 13	35	24		
Screening - Exercise 14	48	41		
Baseline - Exercise 1	55	52		
Baseline - Exercise 2	48	55		
Baseline - Exercise 3	55	38		
Baseline - Exercise 4	69	72		
Baseline - Exercise 5	62	45		
Baseline - Exercise 6	72	76		
Baseline - Exercise 7	55	59		

Baseline - Exercise 8	93	90		
Baseline - Exercise 9	80	69		
Baseline - Exercise 10	83	79		
Baseline - Exercise 11	90	93		
Baseline - Exercise 12	69	76		
Baseline - Exercise 13	41	28		
Baseline - Exercise 14	55	41		
Week 4 - Exercise 1	41	35		
Week 4 - Exercise 2	45	35		
Week 4 - Exercise 3	38	31		
Week 4 - Exercise 4	66	76		
Week 4 - Exercise 5	52	31		
Week 4 - Exercise 6	72	72		
Week 4 - Exercise 7	52	55		
Week 4 - Exercise 8	83	100		
Week 4 - Exercise 9	69	97		
Week 4 - Exercise 10	86	93		
Week 4 - Exercise 11	86	100		
Week 4 - Exercise 12	62	79		
Week 4 - Exercise 13	24	38		
Week 4 - Exercise 14	48	45		
Week 6 - Exercise 1	31	38		
Week 6 - Exercise 2	38	41		
Week 6 - Exercise 3	31	35		
Week 6 - Exercise 4	66	72		
Week 6 - Exercise 5	31	31		
Week 6 - Exercise 6	48	59		
Week 6 - Exercise 7	59	66		
Week 6 - Exercise 8	72	90		
Week 6 - Exercise 9	79	79		
Week 6 - Exercise 10	79	86		
Week 6 - Exercise 11	76	79		
Week 6 - Exercise 12	66	76		
Week 6 - Exercise 13	41	48		
Week 6 - Exercise 14	35	41		
Week 12 - Exercise 1	35	31		
Week 12 - Exercise 2	35	45		
Week 12 - Exercise 3	24	31		
Week 12 - Exercise 4	62	72		
Week 12 - Exercise 5	21	31		
Week 12 - Exercise 6	48	48		
Week 12 - Exercise 7	59	55		
Week 12 - Exercise 8	79	86		
Week 12 - Exercise 9	66	86		
Week 12 - Exercise 10	66	86		
Week 12 - Exercise 11	79	90		
Week 12 - Exercise 12	62	69		
Week 12 - Exercise 13	31	31		
Week 12 - Exercise 14	31	45		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 1: Proportion of patients with >50% risk of falling | NCAS

End point title	Sec. Endpoint 1: Proportion of patients with >50% risk of falling | NCAS

End point description:

Proportion of patients in the NCAS with >50% risk of falling based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Proportion of patients (%)				
Screening	66	66		
Baseline - Day 0	72	69		
Week 4	55	76		
Week 6	35	48		
Week 12	36	52		

Statistical analyses

Statistical analysis title	Chi-square Test - Screening
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[33]
P-value	= 1
Method	Chi-squared

Notes:

[33] - Chi-square Test - Screening (N=58: Arm A=29 | Arm B=29)

Statistical analysis title	Chi-square Test - Baseline
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[34]
P-value	= 0.773
Method	Chi-squared

Notes:

[34] - Chi-square Test - Baseline (N=58: Arm A=29 | Arm B=29)

Statistical analysis title	Chi-square Test - Week 4
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[35]
P-value	= 0.0974
Method	Chi-squared

Notes:

[35] - Chi-square Test - Week 4 (N=58: Arm A=29 | Arm B=29)

Statistical analysis title	Chi-square Test - Week 6
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[36]
P-value	= 0.2862
Method	Chi-squared

Notes:

[36] - Chi-square Test - Week 6 (N=58: Arm A=29 | Arm B=29)

Statistical analysis title	Chi-square Test - Week 12
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[37]
P-value	= 0.2233
Method	Chi-squared

Notes:

[37] - Chi-square Test - Week 12 (N=57: Arm A=28 | Arm B=29)

Secondary: Sec. Endpoint 1: Proportion of patients with >40% risk of falling | NCAS

End point title	Sec. Endpoint 1: Proportion of patients with >40% risk of falling	NCAS

End point description:

Proportion of patients in the NCAS with >40% risk of falling based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Proportion of patients (%)				
Screening	100	100		
Baseline - Day 0	100	97		
Week 4	93	100		
Week 6	83	93		
Week 12	79	90		

Statistical analyses

Statistical analysis title	Chi-square Test - Baseline
Comparison groups	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[38]
P-value	= 0.3131
Method	Chi-squared

Notes:

[38] - Chi-square Test - Baseline (N=58: Arm A=29 | Arm B=29)

Statistical analysis title	Chi-square Test - Week 4
Comparison groups	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v NCAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[39]
P-value	= 0.1501
Method	Chi-squared

Notes:

[39] - Chi-square Test - Week 4 (N=58: Arm A=29 | Arm B=29)

Statistical analysis title	Chi-square Test - Week 6
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[40]
P-value	= 0.2266
Method	Chi-squared

Notes:

[40] - Chi-square Test - Week 6 (N=58: Arm A=29 | Arm B=29)

Statistical analysis title	Chi-square Test - Week 12
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[41]
P-value	= 0.2513
Method	Chi-squared

Notes:

[41] - Chi-square Test - Week 12 (N=57: Arm A=28 | Arm B=29)

Secondary: Sec. Endpoint 1: Average Trunk Sway in Roll-Direction| NCAS

End point title	Sec. Endpoint 1: Average Trunk Sway in Roll-Direction| NCAS

End point description:

Mean dorsoventral imbalance of patients in the NCAS based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Absolute values (°/sec)				
arithmetic mean (standard deviation)				
Screening	5.5 (± 0.99)	5.7 (± 1.19)		
Baseline - Day 0	5.5 (± 0.79)	5.5 (± 1.36)		
Week 4	5.4 (± 1.24)	5.6 (± 1.03)		
Week 6	5.1 (± 1.26)	5.4 (± 1.31)		
Week 12	5.1 (± 1.19)	5.3 (± 1.43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 1: Average Trunk Sway in Pitch-Direction | NCAS

End point title	Sec. Endpoint 1: Average Trunk Sway in Pitch-Direction | NCAS

End point description:

Mean lateral imbalance of patients in the NCAS based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Absolute values (°/sec.)				
arithmetic mean (standard deviation)				
Screening	4.7 (± 0.83)	4.9 (± 0.80)		
Baseline - Day 0	5.0 (± 0.95)	4.9 (± 0.84)		
Week 4	4.8 (± 1.09)	5.0 (± 0.76)		
Week 6	4.6 (± 0.78)	4.8 (± 0.69)		
Week 12	4.7 (± 0.95)	4.9 (± 1.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 4 | FAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 4 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) total score at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-6.6 (± 9.64)	-4.9 (± 9.38)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[42]
P-value	= 0.733
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.5481
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	2.6

Notes:

[42] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 4 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 4 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-2.4 (± 5.08)	-2.0 (± 5.12)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[43]
P-value	= 0.9345
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.07146
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	1.6

Notes:

[43] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 4 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 4 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-2.9 (± 4.09)	-0.8 (± 4.03)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[44]
P-value	= 0.0167
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.7571
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	-0.3

Notes:

[44] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 4 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 4 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-1.3 (± 4.30)	-2.0 (± 4.80)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[45]
P-value	= 0.1388
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	1.233

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.4
upper limit	2.9

Notes:

[45] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 6 | FAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 6 | FAS
End point description:	
Change in Dizziness Handicap Inventory (DHI) total score at week 6 compared to baseline.	
End point type	Secondary
End point timeframe:	
After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).	

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-13.0 (± 13.20)	-8.6 (± 9.52)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback) v FAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[46]
P-value	= 0.1315
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-3.0867
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.1
upper limit	0.9

Notes:

[46] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 6 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 6 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.4 (± 6.26)	-3.8 (± 5.24)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[47]
P-value	= 0.7559
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.311
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	1.7

Notes:

[47] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 6 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at

	week 6 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.6 (± 4.65)	-2.5 (± 4.50)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[48]
P-value	= 0.0416
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.7537
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	-0.1

Notes:

[48] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 6 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 6 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.0 (± 5.23)	-2.4 (± 4.07)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[49]
P-value	= 0.2108
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.0142
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	0.6

Notes:

[49] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 12 | FAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 12 | FAS
End point description:	
Change in Dizziness Handicap Inventory (DHI) total score at week 12 compared to baseline.	
End point type	Secondary
End point timeframe:	
After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).	

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[50]	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-14.0 (± 15.33)	-11.5 (± 9.97)		

Notes:

[50] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[51]
P-value	= 0.4619
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.8052
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	3

Notes:

[51] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 12 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 12 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[52]	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-5.1 (± 6.56)	-4.6 (± 4.72)		

Notes:

[52] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[53]
P-value	= 0.7001
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.4099
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	1.7

Notes:

[53] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 12 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 12 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[54]	56		
Units: Change from baseline				

arithmetic mean (standard deviation)	-5.4 (± 5.68)	-3.5 (± 5.71)		

Notes:

[54] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[55]
P-value	= 0.1621
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.4924
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	0.6

Notes:

[55] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 12 | FAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 12 | FAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[56]	56		
Units: Change from baseline				
arithmetic mean (standard deviation)	-3.5 (± 5.80)	-3.4 (± 3.62)		

Notes:

[56] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[57]
P-value	= 0.7569
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.2747
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.5
upper limit	2

Notes:

[57] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 4 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 4 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) total score at week 4 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-8.6 (± 11.39)	-6.7 (± 8.88)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[58]
P-value	= 0.9143
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.2506
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	4.4

Notes:

[58] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 4 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 4 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 4 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-3.0 (± 5.06)	-2.8 (± 4.91)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[59]
P-value	= 0.9582
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.06541

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	2.4

Notes:

[59] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 4 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 4 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 4 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-3.7 (± 4.51)	-1.0 (± 3.61)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[60]
P-value	= 0.0323
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.1686
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	-0.2

Notes:

[60] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 4 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 4 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 4 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-1.9 (± 4.42)	-3.0 (± 4.23)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[61]
P-value	= 0.0953
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	1.6765
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.3
upper limit	3.7

Notes:

[61] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 6 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 6 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) total score at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-11.7 (± 13.47)	-11.2 (± 9.37)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[62]
P-value	= 0.7658
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.8672
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.9
upper limit	6.7

Notes:

[62] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 6 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 6 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-3.9 (± 6.09)	-4.9 (± 5.39)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[63]
P-value	= 0.3167
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	1.4493
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	4.3

Notes:

[63] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 6 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 6 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.0 (± 4.90)	-2.6 (± 3.82)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[64]
P-value	= 0.3539
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.0908
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	1.2

Notes:

[64] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 6 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 6 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline				

arithmetic mean (standard deviation)	-3.8 (± 4.88)	-3.7 (± 4.07)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[65]
P-value	= 0.5732
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.5666
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	2.6

Notes:

[65] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 12 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 12 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) total score at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[66]	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-11.6 (± 12.85)	-12.1 (± 9.13)		

Notes:

[66] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[67]
P-value	= 0.772
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.8538
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5
upper limit	6.7

Notes:

[67] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 12 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 12 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[68]	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.5 (± 5.75)	-5.0 (± 4.86)		

Notes:

[68] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[69]
P-value	= 0.7406
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.4737
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	3.3

Notes:

[69] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 12 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 12 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[70]	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.4 (± 3.96)	-3.7 (± 4.95)		

Notes:

[70] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[71]
P-value	= 0.7485
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.3808

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.7
upper limit	2

Notes:

[71] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 12 | NCAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 12 | NCAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[72]	29		
Units: Change from baseline				
arithmetic mean (standard deviation)	-2.8 (± 5.48)	-3.4 (± 3.47)		

Notes:

[72] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[73]
P-value	= 0.428
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.9068
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	3.2

Notes:

[73] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 6 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 6 | FAS

End point description:

Average change in hearing ability over frequencies 0.5, 1, 2, 4, 8 kHz at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.5 (± 3.36)	-1.2 (± 5.48)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[74]
P-value	= 0.6409
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.4014
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	1.3

Notes:

[74] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=216.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 6 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 6 | FAS

End point description:

Change in hearing ability at 0.5 kHz at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	55[75]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.2 (± 3.75)	-1.4 (± 5.87)		

Notes:

[75] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 6 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 6 | FAS

End point description:

Change in hearing ability at 1 kHz at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.1 (± 3.35)	-0.2 (± 6.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 6 | FAS	
End point title	Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 6 | FAS

End point description:

Change in hearing ability at 2 kHz at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	55[76]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.1 (± 3.65)	0.4 (± 7.37)		

Notes:

[76] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 6 | FAS	
End point title	Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 6 | FAS

End point description:

Change in hearing ability at 4 kHz at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	55[77]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.8 (± 5.53)	-1.9 (± 6.38)		

Notes:

[77] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 6 | FAS	
End point title	Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 6 | FAS

End point description:

Change in hearing ability at 8 kHz at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	43[78]	47[79]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-2.9 (± 8.49)	-4.1 (± 7.94)		

Notes:

[78] - Data for ten patients missing.

[79] - Data for nine patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 12 | FAS	
End point title	Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 12 | FAS

End point description:

Average change in hearing ability over frequencies 0.5, 1, 2, 4, 8 kHz at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[80]	56		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.2 (± 3.61)	-0.2 (± 6.30)		

Notes:
[80] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[81]
P-value	= 0.2223
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.2307
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	0.8

Notes:
[81] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=216.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 12 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 12 | FAS

End point description:
Change in hearing ability at 0.5 kHz at week 12 compared to baseline.

End point type	Secondary

End point timeframe:
After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[82]	54[83]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-2.1 (± 4.96)	-0.2 (± 7.80)		

Notes:
[82] - Data for two patients missing.
[83] - Data for two patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 12 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 12 | FAS

End point description:

Change in hearing ability at 1 kHz at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[84]	56		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.2 (± 4.51)	-0.1 (± 7.42)		

Notes:

[84] - Data for two patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 12 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 12 | FAS

End point description:

Change in hearing ability at 2 kHz at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[85]	55[86]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	0.2 (± 3.63)	1.0 (± 7.78)		

Notes:

[85] - Data for two patients missing.

[86] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 12 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 12 | FAS

End point description:

Change in hearing ability at 4 kHz at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[87]	55[88]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-2.1 (± 5.25)	-1.4 (± 7.54)		

Notes:

[87] - Data for two patients missing.

[88] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 12 | FAS

End point title	Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 12 | FAS

End point description:

Change in hearing ability at 8 kHz at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	41[89]	47[90]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-2.6 (± 6.52)	-2.3 (± 8.40)		

Notes:

[89] - Data for twelve patients missing.

[90] - Data for nine patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 6 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 6 | NCAS

End point description:

Average change in hearing ability over frequencies 0.5, 1, 2, 4, 8 kHz at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.9 (± 3.14)	-0.3 (± 3.65)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[91]
P-value	= 0.5572
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.5271

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	1.3

Notes:

[91] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=115.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 6 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 6 | NCAS

End point description:

Change in hearing ability at 0.5 kHz at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	28[92]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.7 (± 4.06)	-1.5 (± 3.49)		

Notes:

[92] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 6 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 6 | NCAS

End point description:

Change in hearing ability at 1 kHz at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.6 (± 2.71)	0.3 (± 5.76)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 6 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 6 | NCAS

End point description:

Change in hearing ability at 2 kHz at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	28[93]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.3 (± 3.68)	2.7 (± 5.48)		

Notes:

[93] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 6 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 6 | NCAS

End point description:

Change in hearing ability at 4 kHz at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	28[94]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.8 (± 6.26)	-0.7 (± 5.44)		

Notes:

[94] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 6 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 6 | NCAS

End point description:

Change in hearing ability at 8 kHz at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	20[95]	21[96]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.5 (± 8.68)	-3.9 (± 8.50)		

Notes:

[95] - Data for nine patients missing.

[96] - Data for eight patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 12 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 12 | NCAS

End point description:

Average change in hearing ability over frequencies 0.5, 1, 2, 4, 8 kHz at week 12 compared to baseline

for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[97]	29		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.7 (± 3.78)	0.7 (± 3.56)		

Notes:

[97] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[98]
P-value	= 0.1549
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.3847
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.3
upper limit	0.5

Notes:

[98] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=115.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 12 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 12 | NCAS

End point description:

Change in hearing ability at 0.5 kHz at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[99]	28[100]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.2 (± 5.20)	0.7 (± 6.87)		

Notes:

[99] - Data for one patient missing.

[100] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 12 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 12 | NCAS

End point description:

Change in hearing ability at 1 kHz at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[101]	29		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.5 (± 4.68)	0.3 (± 5.97)		

Notes:

[101] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 12 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 12 | NCAS

End point description:

Change in hearing ability at 2 kHz at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[102]	28[103]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	0.5 (± 3.87)	3.1 (± 5.03)		

Notes:

[102] - Data for one patient missing.

[103] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 12 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 12 | NCAS

End point description:

Change in hearing ability at 4 kHz at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[104]	28[105]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-2.6 (± 5.95)	-0.4 (± 7.17)		

Notes:

[104] - Data for one patient missing.

[105] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 12 | NCAS

End point title	Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 12 | NCAS

End point description:

Change in hearing ability at 8 kHz at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	19[106]	21[107]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.8 (± 6.11)	-2.0 (± 5.90)		

Notes:

[106] - Data for ten patients missing.

[107] - Data for eight patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 4 | FAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 4 | FAS

End point description:

Change in processing time of part A of the trail making test at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-4.6 (± 15.28)	-5.2 (± 18.83)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)

Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[108]
P-value	= 0.7786
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.8146
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5
upper limit	4.9

Notes:

[108] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 4 | FAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 4 | FAS

End point description:

Change in processing time of part B of the trail making test at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-14.2 (± 40.42)	8.8 (± 33.80)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[109]
P-value	= 0.6463
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.9114

Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.5
upper limit	9.6

Notes:

[109] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 4 | FAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 4 | FAS

End point description:

Change in difference of the processing time of part B and part A of the trail making test at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-9.6 (± 43.22)	-3.6 (± 33.24)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[110]
P-value	= 0.84
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.2674
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.7
upper limit	11.2

Notes:

[110] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 6 | FAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 6 | FAS

End point description:

Change in processing time of part A of the trail making test at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-7.4 (± 14.20)	-7.9 (± 19.66)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[111]
P-value	= 0.6444
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.269
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	4.2

Notes:

[111] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 6 | FAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 6 | FAS

End point description:

Change in processing time of part B of the trail making test at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-19.0 (± 35.38)	-20.3 (± 34.20)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[112]
P-value	= 0.4537
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	4.1254
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8
upper limit	15

Notes:

[112] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 6 | FAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 6 | FAS

End point description:

Change in the difference of the processing time of part B and part A of the trail making test at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	53	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-11.6 (± 39.01)	-12.3 (± 34.17)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	other[113]
P-value	= 0.3025
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	5.8658
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.4
upper limit	17.1

Notes:

[113] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 12 | FAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 12 | FAS

End point description:

Change in processing time of part A of the trail making test at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[114]	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-3.1 (± 16.45)	-9.3 (± 16.42)		

Notes:

[114] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[115]
P-value	= 0.1604
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	4.0798
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.6
upper limit	9.8

Notes:

[115] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 12 | FAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 12 | FAS

End point description:

Change in processing time of part B of the trail making test at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[116]	56		
Units: Change from baseline (sec.)				

arithmetic mean (standard deviation)	-21.7 (± 36.09)	-17.1 (± 32.60)		

Notes:

[116] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[117]
P-value	= 0.7095
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.9791
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.5
upper limit	8.5

Notes:

[117] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 12 | FAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 12 | FAS

End point description:

Change in the difference of the processing time of part B and part A of the trail making test at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	FAS - Arm A (EGb 761® + normal vibrotactile feedback)	FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	51[118]	56		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-18.6 (± 41.10)	-7.8 (± 34.77)		

Notes:
[118] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	FAS - Arm A (EGb 761® + normal vibrotactile feedback) v FAS - Arm B (EGb 761® + insensitve vibrotactile feedback)
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	other[119]
P-value	= 0.3725
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-5.2259
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.8
upper limit	6.3

Notes:
[119] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=325.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 4 | NCAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 4 | NCAS

End point description:

Change in processing time of part A of the trail making test at week 4 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-3.2 (± 14.64)	-6.5 (± 12.86)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[120]
P-value	= 0.1284
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	4.607
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.4
upper limit	10.6

Notes:

[120] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 4 | NCAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 4 | NCAS

End point description:

Change in processing time of part B of the trail making test at week 4 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-20.6 (± 43.77)	-6.5 (± 29.56)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[121]
P-value	= 0.7963
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	2.1033
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.1
upper limit	18.4

Notes:

[121] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 4 | NCAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 4 | NCAS

End point description:

Change in difference of the processing time of part B and part A of the trail making test at week 4 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-17.4 (± 49.21)	0.0 (± 31.93)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[122]
P-value	= 0.8594
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	1.5509
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.9
upper limit	19

Notes:

[122] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 6 | NCAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 6 | NCAS

End point description:

Change in processing time of part A of the trail making test at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-6.2 (± 15.22)	-7.6 (± 14.03)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[123]
P-value	= 0.3936
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	2.7552

Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	9.2

Notes:

[123] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 6 | NCAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 6 | NCAS

End point description:

Change in processing time of part B of the trail making test at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-18.2 (± 31.76)	-6.8 (± 23.99)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[124]
P-value	= 0.5017
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-5.0592
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.1
upper limit	9.9

Notes:

[124] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 6 | NCAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 6 | NCAS

End point description:

Change in the difference of the processing time of part B and part A of the trail making test at week 6 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-12.0 (± 38.80)	0.8 (± 23.01)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[125]
P-value	= 0.7048
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-3.0823
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.3
upper limit	13.1

Notes:

[125] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 12 | NCAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 12 | NCAS

End point description:

Change in processing time of part A of the trail making test at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[126]	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-2.8 (± 14.54)	-6.8 (± 11.57)		

Notes:

[126] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[127]
P-value	= 0.1797
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	4.2444
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	10.5

Notes:

[127] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 12 | NCAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 12 | NCAS

End point description:

Change in processing time of part B of the trail making test at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[128]	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-26.6 (± 34.34)	-12.7 (± 26.23)		

Notes:

[128] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[129]
P-value	= 0.9855
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.1239
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.8
upper limit	13.5

Notes:

[129] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 12 | NCAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 12 | NCAS

End point description:

Change in the difference of the processing time of part B and part A of the trail making test at week 12 compared to baseline for patients in the NCAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	NCAS - Arm A (EGb 761® + normal vibrotactile feedback)	NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28[130]	29		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-23.9 (± 39.90)	-5.9 (± 28.07)		

Notes:

[130] - Data for one patient missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	NCAS - Arm A (EGb 761® + normal vibrotactile feedback) v NCAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	57
Analysis specification	Pre-specified
Analysis type	other[131]
P-value	= 0.8901
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	1.0029
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.5
upper limit	15.5

Notes:

[131] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=173.

Secondary: Sec. Endpoint 1: Change of tendency of falling after 4 weeks | AAS

End point title	Sec. Endpoint 1: Change of tendency of falling after 4 weeks | AAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test). Analysis by MMRM.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days)

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change in gSBDT from baseline				

(%)				
arithmetic mean (standard deviation)	-2.2 (± 6.91)	-1.4 (± 8.22)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[132]
P-value	= 0.4358
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.176
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	1.8

Notes:

[132] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 1: Change of tendency of falling after 12 weeks | AAS

End point title	Sec. Endpoint 1: Change of tendency of falling after 12 weeks | AAS

End point description:

Assessment of the tendency of falling in balance situations measured by VertiGuard® RT and using the gSBDT (geriatric Standard Balance Deficit Test). Analysis by MMRM.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days)

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[133]	43		
Units: Change in gSBDT from baseline (%)				
arithmetic mean (standard deviation)	-7.1 (± 8.84)	-4.4 (± 9.06)		

Notes:

[133] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[134]
P-value	= 0.1083
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.8348
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	0.6

Notes:

[134] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 1: Proportion of patients with pathological balance disorders |AAS

End point title	Sec. Endpoint 1: Proportion of patients with pathological balance disorders |AAS

End point description:

Proportion of patients with pathological balance disorders assessed by 14 gSBDT-excercises.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Proportion of patients (%)				
Screening - Exercise 1	50	47		
Screening - Exercise 2	55	54		
Screening - Exercise 3	52	44		
Screening - Exercise 4	69	70		
Screening - Exercise 5	60	49		
Screening - Exercise 6	79	70		
Screening - Exercise 7	50	56		
Screening - Exercise 8	88	95		
Screening - Exercise 9	79	88		
Screening - Exercise 10	74	88		
Screening - Exercise 11	91	95		

Screening - Exercise 12	74	81		
Screening - Exercise 13	45	35		
Screening - Exercise 14	55	47		
Baseline - Exercise 1	62	61		
Baseline - Exercise 2	55	61		
Baseline - Exercise 3	64	56		
Baseline - Exercise 4	79	79		
Baseline - Exercise 5	60	49		
Baseline - Exercise 6	76	79		
Baseline - Exercise 7	60	61		
Baseline - Exercise 8	91	91		
Baseline - Exercise 9	76	74		
Baseline - Exercise 10	81	79		
Baseline - Exercise 11	91	93		
Baseline - Exercise 12	74	79		
Baseline - Exercise 13	48	42		
Baseline - Exercise 14	62	56		
Week 4 - Exercise 1	50	51		
Week 4 - Exercise 2	52	47		
Week 4 - Exercise 3	50	51		
Week 4 - Exercise 4	76	77		
Week 4 - Exercise 5	50	47		
Week 4 - Exercise 6	71	79		
Week 4 - Exercise 7	52	63		
Week 4 - Exercise 8	83	95		
Week 4 - Exercise 9	74	93		
Week 4 - Exercise 10	83	88		
Week 4 - Exercise 11	91	95		
Week 4 - Exercise 12	69	81		
Week 4 - Exercise 13	38	47		
Week 4 - Exercise 14	50	58		
Week 6 - Exercise 1	43	49		
Week 6 - Exercise 2	45	49		
Week 6 - Exercise 3	45	47		
Week 6 - Exercise 4	71	79		
Week 6 - Exercise 5	38	30		
Week 6 - Exercise 6	50	61		
Week 6 - Exercise 7	64	67		
Week 6 - Exercise 8	79	86		
Week 6 - Exercise 9	74	79		
Week 6 - Exercise 10	76	84		
Week 6 - Exercise 11	79	84		
Week 6 - Exercise 12	71	84		
Week 6 - Exercise 13	48	56		
Week 6 - Exercise 14	48	58		
Week 12 - Exercise 1	43	47		
Week 12 - Exercise 2	43	51		
Week 12 - Exercise 3	33	51		
Week 12 - Exercise 4	67	77		
Week 12 - Exercise 5	29	37		
Week 12 - Exercise 6	48	56		
Week 12 - Exercise 7	62	63		

Week 12 - Exercise 8	76	84		
Week 12 - Exercise 9	67	91		
Week 12 - Exercise 10	69	86		
Week 12 - Exercise 11	76	88		
Week 12 - Exercise 12	62	77		
Week 12 - Exercise 13	43	51		
Week 12 - Exercise 14	41	63		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 1: Proportion of patients with >50% risk of falling | AAS

End point title	Sec. Endpoint 1: Proportion of patients with >50% risk of falling | AAS

End point description:

Proportion of patients with >50% risk of falling based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Proportion of patients (%)				
Screening	69	72		
Baseline - Day 0	74	72		
Week 4	57	74		
Week 6	38	58		
Week 12	38	61		

Statistical analyses

Statistical analysis title	Chi-square Test - Screening
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[135]
P-value	= 0.758
Method	Chi-squared

Notes:

[135] - Chi-square Test - Screening (N=85: Arm A=42 | Arm B=43)

Statistical analysis title	Chi-square Test - Baseline
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[136]
P-value	= 0.8586
Method	Chi-squared

Notes:

[136] - Chi-square Test - Baseline (N=85: Arm A=42 | Arm B=43)

Statistical analysis title	Chi-square Test - Week 4
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[137]
P-value	= 0.093
Method	Chi-squared

Notes:

[137] - Chi-square Test - Week 4 (N=85: Arm A=42 | Arm B=43)

Statistical analysis title	Chi-square Test - Week 6
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[138]
P-value	= 0.0645
Method	Chi-squared

Notes:

[138] - Chi-square Test - Week 6 (N=85: Arm A=42 | Arm B=43)

Statistical analysis title	Chi-square Test - Week 12
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[139]
P-value	= 0.0365
Method	Chi-squared

Notes:

[139] - Chi-square Test - Week 12 (N=83: Arm A=40 | Arm B=43)

Secondary: Sec. Endpoint 1: Proportion of patients with >40% risk of falling | AAS

End point title	Sec. Endpoint 1: Proportion of patients with >40% risk of falling | AAS

End point description:

Proportion of patients with >40% risk of falling based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Proportion of patients (%)				
Screening	100	100		
Baseline - Day 0	100	98		
Week 4	95	98		
Week 6	88	93		
Week 12	85	93		

Statistical analyses

Statistical analysis title	Chi-square Test - Baseline
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[140]
P-value	= 0.3201
Method	Chi-squared

Notes:

[140] - Chi-square Test - Baseline (N=85: Arm A=42 | Arm B=43)

Statistical analysis title	Chi-square Test - Week 4
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[141]
P-value	= 0.5428
Method	Chi-squared

Notes:

[141] - Chi-square Test - Week 4 (N=85: Arm A=42 | Arm B=43)

Statistical analysis title	Chi-square Test - Week 6
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[142]
P-value	= 0.4366
Method	Chi-squared

Notes:

[142] - Chi-square Test - Week 6 (N=85: Arm A=42 | Arm B=43)

Statistical analysis title	Chi-square Test - Week 12
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[143]
P-value	= 0.2401
Method	Chi-squared

Notes:

[143] - Chi-square Test - Week 12 (N=83: Arm A=40 | Arm B=43)

Secondary: Sec. Endpoint 1: Average Trunk Sway in Roll-Direction| AAS

End point title	Sec. Endpoint 1: Average Trunk Sway in Roll-Direction| AAS

End point description:

Mean dorsoventral imbalance of patients based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Absolute values (°/sec)				
arithmetic mean (standard deviation)				
Screening	5.7 (± 1.04)	5.8 (± 1.24)		

Baseline - Day 0	5.6 (± 0.87)	5.9 (± 1.58)		
Week 4	5.4 (± 1.20)	5.9 (± 1.30)		
Week 6	5.2 (± 1.28)	6.0 (± 1.65)		
Week 12	5.3 (± 1.20)	5.8 (± 1.70)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 1: Average Trunk Sway in Pitch-Direction | AAS

End point title	Sec. Endpoint 1: Average Trunk Sway in Pitch-Direction | AAS

End point description:

Mean lateral imbalance of patients based on results of the gSBDT.

End point type	Secondary

End point timeframe:

Measured at screening, baseline, after 4 weeks (28 +/- 2 days), 6 weeks (42 +/- 3 days) and 12 weeks (84 +/- 4 days) of treatment, respectively.

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Absolute values (°/sec.)				
arithmetic mean (standard deviation)				
Screening	5.0 (± 1.07)	5.0 (± 0.85)		
Baseline - Day 0	5.2 (± 1.10)	5.1 (± 0.86)		
Week 4	5.1 (± 1.34)	5.2 (± 0.98)		
Week 6	4.8 (± 0.88)	5.2 (± 0.95)		
Week 12	4.9 (± 1.00)	5.2 (± 1.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 4 | AAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 4 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) total score at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-7.0 (± 10.24)	-4.9 (± 8.95)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[144]
P-value	= 0.8252
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.4069
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	3.2

Notes:

[144] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 4 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 4 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-2.6 (± 5.12)	-1.5 (± 4.78)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[145]
P-value	= 0.5812
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.5409
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.5
upper limit	1.4

Notes:

[145] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 4 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 4 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				

arithmetic mean (standard deviation)	-3.0 (± 4.40)	-1.3 (± 3.73)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[146]
P-value	= 0.1383
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.233
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.9
upper limit	0.4

Notes:

[146] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 4 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 4 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-1.4 (± 4.29)	-2.1 (± 4.30)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[147]
P-value	= 0.1761
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	1.1974
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.5
upper limit	2.9

Notes:

[147] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 6 | AAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 6 | AAS
End point description:	
Change in Dizziness Handicap Inventory (DHI) total score at week 6 compared to baseline.	
End point type	Secondary
End point timeframe:	
After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).	

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-11.4 (± 12.78)	-8.1 (± 9.48)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[148]
P-value	= 0.4575
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.7164
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.3
upper limit	2.9

Notes:

[148] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 6 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 6 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-3.7 (± 6.10)	-3.4 (± 5.24)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[149]
P-value	= 0.745
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.3767

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	2.7

Notes:

[149] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 6 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 6 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.1 (± 4.75)	-2.3 (± 3.80)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[150]
P-value	= 0.093
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.587
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.4
upper limit	0.3

Notes:

[150] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 6 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 6 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-3.5 (± 4.77)	-2.3 (± 4.27)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[151]
P-value	= 0.5721
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.5006
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3
upper limit	1.3

Notes:

[151] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in total score at week 12 | AAS

End point title	Sec. Endpoint 2: DHI - Change in total score at week 12 | AAS

End point description:
Change in Dizziness Handicap Inventory (DHI) total score at week 12 compared to baseline.

End point type	Secondary

End point timeframe:
After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[152]	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-12.5 (± 14.84)	-10.3 (± 9.76)		

Notes:

[152] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[153]
P-value	= 0.6657
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.1857
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.6
upper limit	4.3

Notes:

[153] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 12 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'functional impacts' at week 12 | AAS

End point description:
Change in Dizziness Handicap Inventory (DHI) subscore 'functional impacts of disability' at week 12 compared to baseline.

End point type	Secondary

End point timeframe:
After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[154]	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.7 (± 6.55)	-4.1 (± 4.81)		

Notes:

[154] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[155]
P-value	= 0.9141
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.1343
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	2.3

Notes:

[155] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 12 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'physical impacts' at week 12 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'physical impacts of disability' at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[156]	43		
Units: Change from baseline				
arithmetic mean (standard deviation)	-4.8 (± 5.04)	-3.3 (± 5.00)		

Notes:

[156] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[157]
P-value	= 0.2213
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.3211
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	0.8

Notes:

[157] - MMRM as for the primary analysis.

Secondary: Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 12 | AAS

End point title	Sec. Endpoint 2: DHI - Change in subscore 'emotional impacts' at week 12 | AAS

End point description:

Change in Dizziness Handicap Inventory (DHI) subscore 'emotional Impacts of disability' at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[158]	43		
Units: Change from baseline				

arithmetic mean (standard deviation)	-3.1 (± 5.71)	-2.9 (± 3.47)		

Notes:

[158] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[159]
P-value	= 0.7294
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.3517
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.7
upper limit	2.4

Notes:

[159] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 6 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 6 | AAS

End point description:

Average change in hearing ability over frequencies 0.5, 1, 2, 4, 8 kHz at week 6 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.9 (± 3.19)	-0.6 (± 5.83)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[160]
P-value	= 0.7377
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.351
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4
upper limit	1.7

Notes:

[160] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=168.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 6 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 6 | AAS

End point description:

Change in hearing ability at 0.5 kHz at week 6 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	42[161]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.7 (± 3.80)	-1.1 (± 6.47)		

Notes:

[161] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 6 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 6 | AAS

End point description:

Change in hearing ability at 1 kHz at week 6 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.9 (± 3.53)	0.2 (± 7.25)		

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 6 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 6 | AAS

End point description:

Change in hearing ability at 2 kHz at week 6 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	42[162]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.5 (± 3.56)	1.3 (± 7.99)		

Notes:

[162] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 6 | AAS	
End point title	Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 6 | AAS

End point description:

Change in hearing ability at 4 kHz at week 6 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	42[163]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.1 (± 5.87)	-1.2 (± 6.70)		

Notes:

[163] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 6 | AAS	
End point title	Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 6 | AAS

End point description:

Change in hearing ability at 8 kHz at week 6 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33[164]	35[165]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.5 (± 8.15)	-3.6 (± 8.56)		

Notes:

[164] - Data for nine patients missing.

[165] - Data for eight patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 12 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 - 8 kHz) at week 12 | AAS

End point description:

Average change in hearing ability over frequencies 0.5, 1, 2, 4, 8 kHz at week 12 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[166]	43		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-0.8 (± 3.65)	0.1 (± 6.69)		

Notes:

[166] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[167]
P-value	= 0.3346
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.1733
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	1.2

Notes:

[167] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=168.

Secondary: Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 12 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (0.5 kHz) at week 12 | AAS

End point description:

Change in hearing ability at 1 kHz at week 12 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[168]	41[169]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.7 (± 4.98)	-0.1 (± 8.68)		

Notes:

[168] - Data for two patients missing.

[169] - Data for two patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 12 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (1 kHz) at week 12 | AAS

End point description:

Change in hearing ability at 1 kHz at week 12 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[170]	43		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.2 (± 4.67)	-0.2 (± 7.84)		

Notes:

[170] - Data for two patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 12 | AAS	
End point title	Sec. Endpoint 3: Change in hearing ability (2 kHz) at week 12 | AAS

End point description:

Change in hearing ability at 2 kHz at week 12 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[171]	42[172]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	0.4 (± 3.74)	1.3 (± 8.47)		

Notes:

[171] - Data for two patients missing.

[172] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 12 | AAS	
End point title	Sec. Endpoint 3: Change in hearing ability (4 kHz) at week 12 | AAS

End point description:

Change in hearing ability at 4 kHz at week 12 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[173]	42[174]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.9 (± 5.60)	-1.2 (± 8.08)		

Notes:

[173] - Data for two patients missing.

[174] - Data for one patient missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 12 | AAS

End point title	Sec. Endpoint 3: Change in hearing ability (8 kHz) at week 12 | AAS

End point description:

Change in hearing ability at 8 kHz at week 12 compared to baseline for patients in the AAS.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31[175]	35[176]		
Units: Change from baseline (dB HL)				
arithmetic mean (standard deviation)	-1.5 (± 6.34)	-1.6 (± 8.23)		

Notes:

[175] - Data for eleven patients missing.

[176] - Data for eight patients missing.

Statistical analyses

No statistical analyses for this end point

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 4 | AAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 4 | AAS

End point description:

Change in processing time of part A of the trail making test at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-6.0 (± 13.93)	-8.7 (± 15.00)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[177]
P-value	= 0.3801
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	2.1665
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.7
upper limit	7.1

Notes:

[177] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 4 | AAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 4 | AAS

End point description:

Change in processing time of part B of the trail making test at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-18.9 (± 41.15)	-9.9 (± 29.80)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[178]
P-value	= 0.7286
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.3949
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.1
upper limit	11.3

Notes:

[178] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 4 | AAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 4 | AAS

End point description:

Change in difference of the processing time of part B and part A of the trail making test at week 4 compared to baseline.

End point type	Secondary

End point timeframe:

After 4 weeks of treatment - baseline to week 4 (28 +/- 2 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-12.9 (± 45.70)	-1.2 (± 30.61)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)

Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[179]
P-value	= 0.7255
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-2.5315
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.8
upper limit	11.8

Notes:

[179] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 6 | AAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 6 | AAS

End point description:

Change in processing time of part A of the trail making test at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-8.5 (± 15.10)	-10.0 (± 16.11)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[180]
P-value	= 0.71
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.9707

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.2
upper limit	6.1

Notes:

[180] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 6 | AAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part B at week 6 | AAS

End point description:

Change in processing time of part B of the trail making test at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-22.9 (± 35.11)	-16.5 (± 32.28)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[181]
P-value	= 0.9535
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	0.3622
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12
upper limit	12.7

Notes:

[181] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 6 | AAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 6 | AAS

End point description:

Change in the difference of the processing time of part B and part A of the trail making test at week 6 compared to baseline.

End point type	Secondary

End point timeframe:

After 6 weeks of treatment - baseline to week 6 (42 +/- 3 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	42	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-14.4 (± 40.71)	-6.5 (± 32.40)		

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	85
Analysis specification	Pre-specified
Analysis type	other[182]
P-value	= 0.8189 [183]
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	1.529
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.7
upper limit	14.8

Notes:

[182] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.
[183] - MMRM as for the primary analysis.

Secondary: Sec. Endpoint 4: Change in processing time - trail making test part A at week 12 | AAS

End point title	Sec. Endpoint 4: Change in processing time - trail making test part A at week 12 | AAS

End point description:

Change in processing time of part A of the trail making test at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[184]	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-4.6 (± 14.76)	-9.3 (± 13.84)		

Notes:

[184] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[185]
P-value	= 0.2015
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	3.4424
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.9
upper limit	8.8

Notes:

[185] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 12 | AAS

End point title	Secondary: Sec. Endpoint 4: Change in processing time - trail making test part B at week 12 | AAS

End point description:

Change in processing time of part B of the trail making test at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[186]	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-27.0 (± 33.74)	-19.1 (± 30.75)		

Notes:

[186] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm A (EGb 761® + normal vibrotactile feedback) v AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[187]
P-value	= 0.9511
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-0.3171
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.6
upper limit	9.9

Notes:

[187] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Secondary: Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 12 | AAS

End point title	Sec. Endpoint 4: Change in difference of processing time of trail making test part B and part A at week 12 | AAS

End point description:

Change in the difference of the processing time of part B and part A of the trail making test at week 12 compared to baseline.

End point type	Secondary

End point timeframe:

After 12 weeks of treatment - baseline to week 12 (84 +/- 4 days).

End point values	AAS - Arm A (EGb 761® + normal vibrotactile feedback)	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback)		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	40[188]	43		
Units: Change from baseline (sec.)				
arithmetic mean (standard deviation)	-22.4 (± 37.62)	-9.9 (± 32.50)		

Notes:

[188] - Data for two patients missing.

Statistical analyses

Statistical analysis title	Mixed Model Repeated Measures (MMRM)
Comparison groups	AAS - Arm B (EGb 761® + insensitive vibrotactile feedback) v AAS - Arm A (EGb 761® + normal vibrotactile feedback)
Number of subjects included in analysis	83
Analysis specification	Pre-specified
Analysis type	other[189]
P-value	= 0.8108
Method	Mixed models analysis
Parameter estimate	MMRM - Difference of treatment arms
Point estimate	-1.3192
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.3
upper limit	9.6

Notes:

[189] - MMRM as for the primary analysis.
Note: The number of subjects included in the analysis was set automatically by the database. The actual number of values contributing to this statistics is n=253.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events (AEs) were reported after from the day of first intake of study medication until end of study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	SAF - Arm A (EGb 761® + normal vibrotactile feedback)

Reporting group description:

Safety Analysis Set of treatment arm A (EGb 761® + normal vibrotactile feedback).
The SAF includes all randomized patients that received at least one dose of the study medication and/or who performed at least one day of balance training. Patients were allocated to treatment arms in the SAF according to their actual treatment, i.e. correcting potential erroneous randomizations.

Reporting group title	SAF - Arm B (EGb 761® + insensitive vibrotactile feedback)

Reporting group description:

Safety Analysis Set of treatment arm B (EGb 761® + insensitive vibrotactile feedback).
The SAF includes all randomized patients that received at least one dose of the study medication and/or who performed at least one day of balance training. Patients were allocated to treatment arms in the SAF according to their actual treatment, i.e. correcting potential erroneous randomizations.

Serious adverse events	SAF - Arm A (EGb 761® + normal vibrotactile feedback)	SAF - Arm B (EGb 761® + insensitive vibrotactile feedback)	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 59 (6.78%)	1 / 61 (1.64%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian adenoma			
subjects affected / exposed	1 / 59 (1.69%)	0 / 61 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 59 (0.00%)	1 / 61 (1.64%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			

Circulatory collapse			
subjects affected / exposed	1 / 59 (1.69%)	0 / 61 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 59 (1.69%)	0 / 61 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 59 (1.69%)	0 / 61 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	SAF - Arm A (EGb 761® + normal vibrotactile feedback)	SAF - Arm B (EGb 761® + insensitive vibrotactile feedback)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 59 (44.07%)	24 / 61 (39.34%)	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	2 / 59 (3.39%)	2 / 61 (3.28%)	
occurrences (all)	2	2	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 59 (0.00%)	3 / 61 (4.92%)	
occurrences (all)	0	3	
Sciatica			
subjects affected / exposed	1 / 59 (1.69%)	2 / 61 (3.28%)	
occurrences (all)	1	2	
Dizziness			
subjects affected / exposed	2 / 59 (3.39%)	0 / 61 (0.00%)	
occurrences (all)	2	0	
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	2 / 59 (3.39%)	1 / 61 (1.64%)	
occurrences (all)	2	1	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	1 / 59 (1.69%)	2 / 61 (3.28%)	
occurrences (all)	1	2	
Rash			
subjects affected / exposed	0 / 59 (0.00%)	2 / 61 (3.28%)	
occurrences (all)	0	2	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 59 (3.39%)	1 / 61 (1.64%)	
occurrences (all)	2	1	
Arthralgia			
subjects affected / exposed	0 / 59 (0.00%)	2 / 61 (3.28%)	
occurrences (all)	0	2	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	7 / 59 (11.86%)	5 / 61 (8.20%)	
occurrences (all)	7	5	
Cystitis bacterial			
subjects affected / exposed	0 / 59 (0.00%)	2 / 61 (3.28%)	
occurrences (all)	0	2	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 November 2014	Protocol Version 2.0 - [first effective Version]; Changes due to EC comments on initial submission
02 April 2015	Protocol Version 3.0; more precise description of the timing of the training
02 August 2017	Protocol Version 4.0; adaptation of adverse event notification due to changes of sponsor SOPs, Sample Size Re-estimation including study timelines; implementation of Quality assurance procedures according to IVH E6 (R2); Update on publication rules.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

At a Blind Data Review Meeting, differences between centers in adjusting the sensitivity of neurofeedback during balance training with VertiGuard® RT were noted, which may have affected the primary outcome (Center 3 and possibly Center 2).

Notes: