Original Article

The Treatment of Vertigo With a Digital Health App

Findings of the Prospective Randomized Controlled GEVE-I Trial

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Summary

Background: Vestibular vertigo is common and frequently leads to inability to work. We studied the clinical efficacy and safety of a digital health app (VH90D) for the treatment of vestibular vertigo.

Methods: We conducted a confirmatory, prospective, single-blinded, randomized, group-controlled, single-center, two-arm superiority trial (n = 212). The 106 patients in the intervention group were treated with the app, and the other 106 received treatment as usual (TAU) with standard physiotherapy. The primary endpoint was the vertigo symptom score (VSS-sf-VER) at 12 weeks. The trial was registered in the German Clinical Trials Register (DRKS00024188).

Results: The mean intergroup difference in the change of VSS-sf-VER score from baseline to week 12 was −7.9 points (95% confidence interval [−9.5; −6.2]; Cohen's d 1.55). The vertigo intensity score fell by an average of 12.7 points (clinically important difference [CID] −5 points; [−14.1; −11.2]) in the intervention group and 2.7 points (CID −5 points; [−3.7; −1.7]) in the TAU group (physiotherapy).

Conclusion: The digital health app VH90D markedly reduced vertigo, with greater efficacy than the median of six 20-minute physiotherapy sessions.

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Dizziness and vertigo are common reasons for medical consultations (1, 2). Among adults, the lifetime prevalence of dizziness of any type is estimated at 23.2% (3) and the lifetime prevalence of vestibular vertigo severe enough to interfere with daily activities is 7.8% (1). The clinical standard of care for chronic vestibular vertigo includes balance-improving exercise therapy (4).

The digital health app used in this study (VH90D) involves a sensorimotor, multimodal vertigo treatment program for use at home. The major therapeutic principle of the app comprises diagnosis-adjusted sensorimotor vestibular exercise programs: the Adaptive Balance Eye and Vision (ABEV) exercises (5, 6). The performance of these exercises stimulates the sensory organs and therefore the brain. This sensorimotor brain stimulation, the principal mechanism of action of the app's ABEV program, is intended to induce central vestibular compensation (CVC), i.e., a neuronal learning process (4, 7, 8). Thus, as long as central vestibular compensation is achieved, the app may be effective irrespective of the underlying peripheral disease. The app includes:

- Specific cognitive behavioral therapy interventions for coping with vertigo-associated stress, vertigo-induced sleep disorders, and vertigo-related anxiety
- Health education providing adequate information about the underlying disease models, with the aim of improving therapy adherence
- Relaxation techniques such as progressive muscle relaxation and autogenic training to reduce unwanted somatosensory responses
- The Otago Exercise Program (9) as a training option in muscle atrophy of the lower extremities

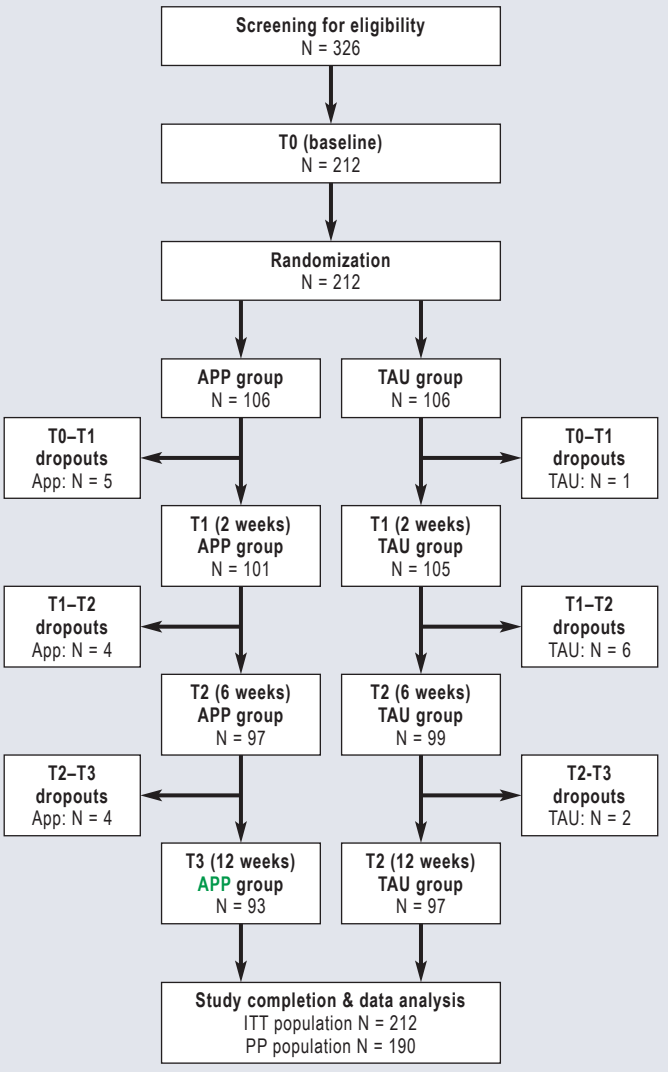
The training program of the digital app is adapted to the underlying disease, e.g., in patients with benign paroxysmal positional vertigo.

To investigate the clinical efficacy and safety of the digital app, the present German Vertigo trial (GEVE I) was designed as a confirmative, prospective, single-blinded, randomized, group-controlled, single-center, two-arm trial with active safety surveillance.

Materials and methods

The Vertidisan app (VH90D-1.0.2) was provided by the manufacturer (Digitineers,

Figure 1



Flowchart of patient allocation
APP, intervention with the digital health app; ITT, intention to treat; PP per protocol; TAU, treatment as usual (physiotherapy)

Tübingen, Germany). The clinical investigation plan was approved by the ethics committee of the Medical Association of the Federal State of Baden-Württemberg, under the appraisal number F-2021–157. The study was registered at the German Registry for Clinical Studies (DRKS00024188, https://www.drks.de/search/de/trial/DRKS00024188) where the clinical investigation plan, including the statistical analysis plan, was deposited.

Briefly, this study was a randomized controlled trial (RCT) with treatment as usual (TAU; physiotherapy) in the control group and 12 weeks' treatment with the app (VH90D) in the experimental group. Patients in the TAU group received physical therapy/physiotherapy (at least six individual sessions, 20 minutes each, corresponding to the usual number of exercise units per prescription for patients with statutory health insurance in Germany) and were offered the app after 12 weeks. No influence was exerted on timing, possible waiting time or additional physiotherapy sessions. Patients could go to the physiotherapist of their choice, so the physiotherapists' previous experience of treating vestibular disorders was not controlled for. *Figure 1* shows the overall study design and procedures. The principal steps included enrolment, allocation, and follow-up. The patients were recruited via advertisements in local newspaper and by informing local physicians' offices. The single-center study was performed at the clinical study center Tübingen Kelternturm (Tübingen, Germany) and was conducted from 10 October 2022 to 22 March 2023. A CONSORT 2025 (10) checklist on the trial is provided in *eTable 1*.

Randomization and blinding are described in the *eMethods*.

A total of 326 individuals were screened based on inclusion and exclusion criteria. The main inclusion criteria were benign paroxysmal positional vertigo (BPPV), labyrinthine trauma, labyrinthitis, persistent postural-perceptual dizziness (PPPD), tumors of the skull base and cerebellopontine angle, presbyvestibulopathy, Menière's disease, vestibular migraine, superior semicircular canal dehiscence syndrome, acute vestibular syndrome, vestibular neuritis, vestibular paroxysmia, unilateral or bilateral vestibulopathy, sudden hearing loss with vestibular involvement, toxic vestibulopathy, and idiopathic vertigo.

The clinical variables were vertigo, stress, autonomic responses/anxiety, and quality of life (QoL). The primary efficacy variable was the score on the German version of the Vertigo Symptom subscale, VSS-sf-VER (11, 12) after 12 weeks (T3). The primary objective was the intergroup comparison of the changes from T0 to T3. The secondary endpoints were evaluated in a predetermined confirmatory test sequence *(eMethods)*. This article focuses on the primary outcome, i.e., analysis of the VSS-sf-VER results.

The primary evaluation was conducted as an intention-to-treat (ITT) analysis. Dropouts were firstly replaced by reference-based multiple imputations (jump to reference [JTR]). Other substitution methods were applied for sensitivity analyses (e.g., last observation carried forward, baseline carried forward, and total mean replacement).

Analysis of covariance (ANCOVA) was performed, with baseline value as covariate and treatment group as factor.

Wilcoxon–Mann–Whitney tests were performed for sensitivity analysis. All primary endpoints were analyzed using two-sided tests, with α = 5%. All other statistical analyses were performed exploratorily with descriptive interpretation of p-values and 95% confidence intervals; for subgroups the separate effects are described by means of 95% confidence intervals.

Demographic results

Our analysis included all 212 ITT patients (100 men and 112 women). The TAU group was older (64.7 years) than the APP group (61.6 years) *(eTable 2)*. The largest diagnosis groups were patients with unilateral or bilateral vestibulopathy (N = 77, 36%), BPPV (N = 34, 16%), PPPD (N = 29, 14%), vestibular migraine (N = 27, 13%), vestibular neuropathy (N = 23, 11%), presbyvestibulopathy (N = 22, 10%) and Menière's disease (N = 12, 6%). The baseline demographics did not differ meaningfully between the per-protocol (PP) population and the ITT population.

Efficacy results

Vertigo intensity was measured using the German version of the validated Vertigo Symptom Subscale, VSS-sf-VER. A change of five points (15% of the total range of 32, cf. IQWIG 2022) (13) was defined as a clinically important difference (CID) in the VSS score. Thus, a score difference of five or more points indicates a clinically relevant change. Using JTR imputations, the statistical efficacy comparison of the two ITT groups resulted in a least-square mean difference (adjusted by ANCOVA) between the groups of –7.9 ([–9.5; –6.2]; Cohen's d: 1.55) points.

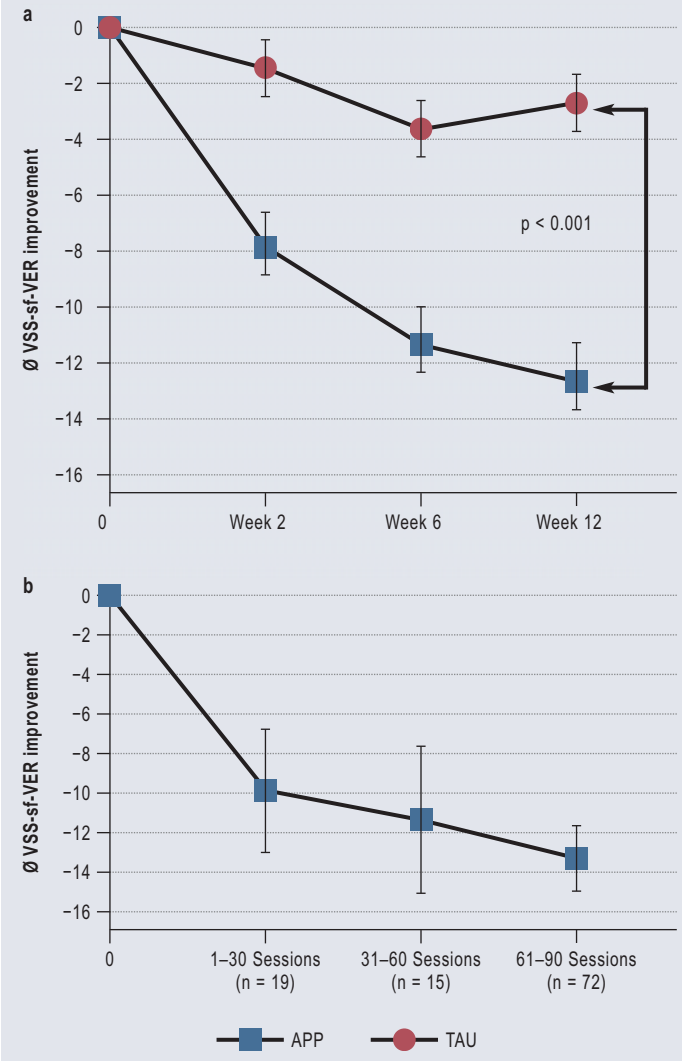
Both the APP group and the TAU group (physiotherapy) exhibited a statistically significant improvement in the VSS-sf-VER score from baseline to week 12 in the ITT population. From baseline to week 12 *(Figure 2a, eTable 1)* the VSS-sf-VER score decreased by a mean of –12.7 points (-66.2%, [–14.1; –11.2]; p < 0.001) in the APP group and by a mean of –2.7 points in the TAU (physiotherapy) group (–16.9%; [–3.7 to –1.7]; p = 0.001). The APP group, but not the physiotherapy group (TAU), reached CID status *(Table)*.

In the responder analysis of ITT (JTR) patients *(Figure 3)*, 93 (87.7%) of the app users were responders after 12 weeks. Responders were defined as patients who achieved the above-mentioned CID, i.e., improvement of the VSS score by 5 points. In the TAU group (physiotherapy), 27 participants (25.5%) were responders. The group comparison demonstrated differences between the APP group and the TAU group (physiotherapy) (response rate difference 62.3% [51.9; 72.6]; p < 0.001) *(Figure 3)*.

Furthermore, a difference was found between the absolute VSS-sf-VER scores of the two groups after 12 weeks. Within the APP intervention group (ITT, JTR), the scores exhibited a mean end value of 6.47 (SD 6.18) and a median of 4.48 points. The mean and median values in the TAU group were 13.30 (SD 5.67) and 13.50, respectively, after the 12-week period.

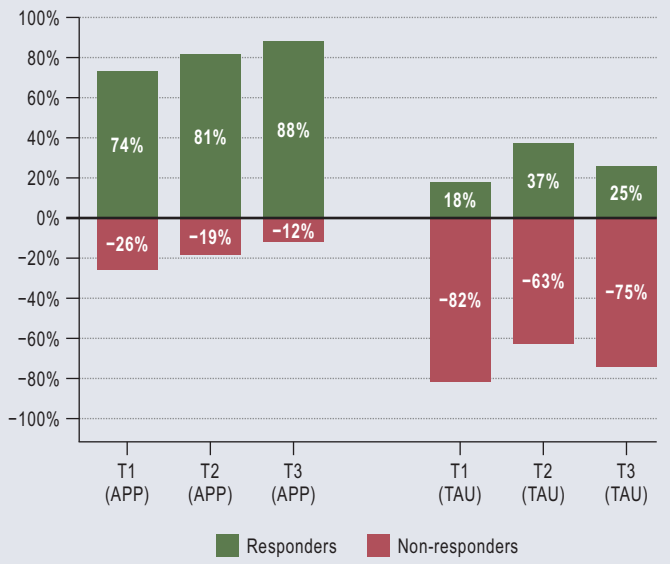
Moreover, a higher number of completed digital app sessions seemed to contribute to an increased efficacy of the app, as depicted in *Figure 2b*. In a post-hoc analysis after 12 weeks, patients who had completed 1–30 sessions with the app showed an average improvement of 9.93

Figure 2



Change in vertigo intensity during the study.
VSS-sf-VER score (score range: 0–32); the bars indicate the confidence interval (95% CI).
a) Average score improvement in the APP and TAU groups. Vertigo intensity change (delta) indicated by VSS-sf-VER score. At T3, the final group difference (ANCOVA) is indicated, which is the primary efficacy variable of the study. Confirmatory group comparison reveals a statistically significant mean treatment difference (least squares [LS] means) between the APP group and the TAU group (p < 0.001). Ordinate: delta of absolute VSS score. Rectangles: intragroup deltas of the APP group; points: intragroup deltas of the TAU group.
b) Average vertigo improvement depending on the number of treatment sessions (APP group).The reduction in VSS-sf-VER score was dose dependent. Number of patients/indication provided in *eTable 6*.
APP, Intervention with the digital health app; TAU, treatment as usual (physiotherapy)

Figure 3



Percentages of responders and non-responders.
Responders were predefined as exhibiting improvement of at least 15% on the VSS-sf-VER scale (or at least 5 points).
APP, Intervention with the digital health app; TAU, treatment as usual (physiotherapy)

points on the VSS-sf-VER scale. For patients who used the app 31–60 times and 61–90 times, respectively, this improvement increased to 11.40 points and 13.63 points.

In a subgroup analysis of underlying diseases, the app showed clinical efficacy in different peripheral vertigo diseases. *Figure 4* shows the forest plot of the group comparison of T0–T3 changes for different subgroup analyses. The diagnoses investigated included BPPV, bilateral and unilateral vestibulopathy, vestibular neuropathy, and vestibular migraine, as well as PPPD as comorbidity. Furthermore, sex, a pretreatment tendency towards falling, duration of illness, paroxysmal or persistent forms of dizziness type as well as permitted occasional adjunctive treatment by means of physiotherapy (in the experimental group) or permitted occasional use of medications had no major influence on the efficacy of the app *(eFigure)*.

To investigate safety, we performed active surveillance of adverse events (AE). Among 29 patients of the APP group, we observed the following reversible adverse events: dizziness, nausea, balance problems, neck pain, headache, blurred vision, tunnel vision, tinnitus, musculoskeletal pain, back tension, muscle tension, fatigue, knee pain, and loss of appetite. In the physiotherapy group, 20 participants exhibited similar reversible AE as in the APP group. Participants in the physiotherapy group (TAU) experienced two additional permanent AE, namely sudden hearing loss and tinnitus, which were categorized as physiotherapy-induced serious AE.

Discussion

The clinical standard of care for vertigo may include medication, physiotherapy, psychotherapy, and, rarely, surgery. In chronic vertigo, however, evidence-based drug treatment is frequently not available. In the acute phase of peripheral vertigo, physicians regularly prescribe cortisone or antivertigo drugs that interact with histamine, muscarinic, dopamine, serotonin, and/or GABA receptors (14). Many of these drugs should only be given for a limited period of time (4). In the chronic treatment scenario, drug therapy is often based purely on a physician's personal experience, as there is often no published scientific evidence (4, 15–18). In addition, medication may be limited by AE (14).

Here we present the results of a single-center, randomized, clinical trial using a digital health app to treat patients suffering from peripheral vertigo. We found that 87.7% of the app users were responders, compared with 25.5% in the physiotherapy group.

The amelioration of vertigo symptoms was similar irrespective of the underlying peripheral vertigo diagnosis. This may be explained by the expected central vertigo compensation mechanism of action in the brain (4, 19), which may be similar in peripheral vestibular diseases. In terms of age, there is a tendency towards lower effectiveness in older patients, which can be explained by the expected delayed central compensation at advanced age. Furthermore, 34 patients (16%) with BPPV were included in the study. Instruction in the positional maneuvers was therefore possible via the app we used, but not verification of the correct performance of the exercises. In the event of doubt about proper execution of the exercises, additional physiotherapy or verification of compliance by the treating physician may be beneficial.

One potential reason for the poorer efficacy of physiotherapy in comparison with the app is the brevity of the treatment, from six to 20 individual sessions of 20 minutes each, compared with 20 minutes' treatment daily for 90 days with the app. In this study, performance of exercises at home by patients in the physiotherapy group was not documented and the suitability of the physiotherapy exercises was not monitored. Patients could visit a physiotherapist of their own choice irrespective of the latter's expertise in treating vestibular disorders, reflecting routine clinical care in Germany. Moreover, only 51.4% of patients had started with physiotherapy at T1 (after 2 weeks), again mirroring the routine care situation in Germany. Specialized (and daily) physiotherapy or daily non-digital treatment from day 1 as control may have been more effective than the physiotherapy in this study. Indeed, a Cochrane review reported a statistically significant effect of vestibular exercises on rehabilitation (odds ratio (OR) 2.67, [1.85; 3.86; four studies, 565 participants) (20). The study therefore does not per se prove that the app is more efficacious than a non-digital standardized daily multimodal vestibular rehabilitation therapy for 90 days, which was not performed in the TAU (physiotherapy) group—and on practical as well as economic grounds is not routinely carried out in Germany. Another potential reason for the difference in results between the APP group and the TAU group (physiotherapy) is the differing distribution of vestibular disorders in the two groups. There were higher proportions of patients with bilateral vestibulopathy (26% vs 17%) and idiopathic vertigo (12% vs 3%) in the TAU (physiotherapy) than in the APP group, and both

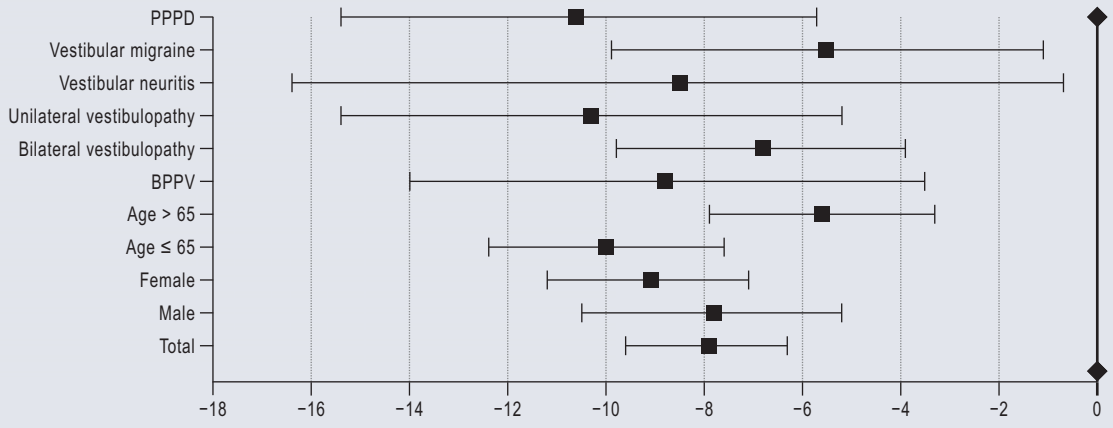
Table

Analysis of vertigo on the basis of the score on the Vertigo Symptom Scale–Short Form vertigo (VSS-sf-VER)*1

Treatment	Mean	SD	Median	Range	LS Mean Difference		p-value*2
					SE	[95% CI]	
Change from baseline to week 2							
APP	−7.83	6.50	−8.00	(−27 to 11)	−4.9 (0.8)	[−6.5; −3.3]	< 0.001
TAU	−1.43	5.36	−1.00	(−19 to 11)			
Change from baseline to week 6							
APP	−11.33	7.02	−12.00	(−30 to 9)	−5.6 (0.8)	[−7.2; −4.0]	< 0.001
TAU	−3.60	5.27	−4.00	(−18 to 9)			
Change from baseline to week 12							
APP	−12.65	7.29	−13.36	(−31 to 9)	−7.9 (0.9)	[−9.5; −6.2]	< 0.001
TAU	−2.68	5.39	−2.00	(−19 to 14)			
Cohen's d for change from baseline to week 12					d = 1.55		

*1 n = 106; ITT; *2 intergroup comparison
Change from baseline: post-baseline values minus baseline values. Adjusted LS means and p values from ANCOVA with group and baseline value as covariate, imputations by jump to reference (JTR).
APP, Digital health app Vertidisan (VH90D); CI, confidence interval; ITT, intention to treat; LS, least square; SD, standard deviation; SE, standard error; TAU, treatment as usual
The VSS-sf-VER scores at the individual time points are presented in eTable 5 together with the changes relative to baseline.

Figure 4



Forest plot of APP treatment effect for VSS-sf-VER subgroups (ITT): Adjusted LS mean and 95% confidence intervals of APP treatment effect as determined by group comparison of changes from T0 to T3. The black square indicates the mean value of the observed treatment effect. The horizontal line represents the 95% confidence interval. The vertical line (no-effect line, right) marks the point at which there is no treatment effect on the measured end point for the respective subgroup. With the exception of the subgroups female/male, all presented subgroup analyses were planned a priori. A forest plot depicting additional subgroups can be found in the *eFigure*.
APP, Intervention with the digital health app; BPPV, benign paroxysmal positional vertigo; ITT, intention to treat; LS, least squares; VSS-sf-VER, Vertigo Symptom Scale–Short Form vertigo

are more difficult to treat with physiotherapy alone than, for example, BPPV. In addition, the patients that used the app were slightly younger (mean 62 vs. 65 years) with a potentially faster rate of recovery.

In addition, this study compared the multimodal approach of the app with physiotherapy alone, rather than with multimodal treatment. Another bias of the present study is the single blinding, a double-blind design being methodologically infeasible. Potential further sources of bias are the higher baseline values of the primary variable in the APP group and the above-mentioned differing distribution of the vertigo diagnoses in the two groups. However, these two factors cannot fully explain the difference seen between the groups. Moreover, selection bias could confound the results in the APP group, since 32% of patients completed 60 sessions or fewer.

Furthermore, the study was limited to 3 months' follow-up, with no data on longer-term effects.

Data sharing
Individual participant data underlying the results reported will be shared after anonymization upon reasonable request (research proposal) to the first author within 5 years of publication.

Note
The work for this study was part of the PhD thesis of JP. A summary of the results has already been published in German Registry for Clinical Studies: https://www.drks.de/search/de/trial/DRKS00024188.

Conflict of interest statement
This study was sponsored by Digitineers GmbH & Co KG, Tübingen, Germany. The sponsor was involved in the planning and monitoring of the study. The management and shareholders of the sponsoring company overlap. Michael Bulitta, Daniel Schmitz, and Jannik Pieper were paid for performing statistical analyses and Walter Lehmacher for statistical consulting in the planning and analysis of this study. The study was conducted in facilities provided by the sponsor, including diagnostic services. Manuscript writing was assisted by the sponsor.

The authors declare that no further conflict of interest exists.

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Supplementary material
Complete list of references, eReferences, eMethods, eTables, eFigure:
www.aerzteblatt-international.de/m2025.0232

Supplementary material to accompany the article

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eMETHODS

eMaterials and Methods

Randomization and blinding

Block randomization was utilized to minimize allocation bias. Blinding was achieved by the use of envelopes, as described by Doig and Simpson (e1). Sustained blinding of the patients was not feasible. Investigators collecting the clinical study endpoints were blinded to the patient group. For ethical and practical reasons, a separate safety/technology group was established. For active adverse event (AE) surveillance, participants were asked about such events, using an AE checklist, at T1–T3.

Secondary endpoints

The secondary endpoints were evaluated in the following predetermined confirmatory test sequence and will be published elsewhere:

Intergroup comparison of the changes from T0–T3:

- In the Dizziness Handicap Inventory (DHI) (e2)
- In the Clinical Global Impression scores (e3) CGI-I (improvement) and CGI-S (severity)
- In the distress thermometer (e4)
- In the vertigo autonomic responses–anxiety score (VSS-sf-AA) (e5, e6)
- In the quality of life (QoL) score SF-36 (e7).

Results

Adherence was defined as completion of a session or exercise (correctly or otherwise), compliance as correct execution of the exercise.

Apart from the early dropouts ($N_{APP} = 5$; $N_{TAU} = 1$) all APP group patients (N = 101/100%) had started the exercises by visit T1 (2 weeks), whereas no more than 51.4% (54/105) of physiotherapy patients had started their treatment by T1. At visit T3 (12 weeks) N = 3 patients in the physiotherapy group had not yet succeeded in starting physiotherapy.

Adherence of APP patients to the 90 planned sessions with the app was 82.8% *(eTable 4)*. Most patients used the app 7 days/week (52.69%). The mean was 5.26 days, the median 7 days *(eTable 3)*. In the control group 94/97 patients received at least one therapy session, the majority of them six sessions (mean 5.74, median 6). Adherence to the physiotherapy was defined as the proportion of the planned total of 582 sessions (N = 97) represented by the 557 sessions attended (N = 97), resulting in an adherence of 95.7% to the six planned sessions.

Thirteen of 93 APP group patients did not perform all of the exercises precisely as prompted by the digital app. Consequently, in the APP group compliance of 86.0% was calculated: the relative number of patients who performed the exercises exactly as proposed by the app (N = 80) compared with the total number of patients (N = 93, *eTable 3*). In the physiotherapy group 88/95 patients reported full compliance with their therapy plan including home exercises, resulting in a compliance rate of 92.63%.

Section/topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	1
	1b	Structured summary of the trial design, methods, results, and conclusions	2
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	4
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	4
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	15
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	4, 15
	5b	Financial and other conflicts of interest of the manuscript authors	/ (Journal)
Introduction			
Background and rationale	6	Scientific background and rationale	3
Objectives	7	Specific objectives related to benefits and harms	3
Methods			
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	/
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)	4-5

Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	/
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted	4
Eligibility criteria	12a	Eligibility criteria for participants	5
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)	/
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	3,4
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	6
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	CIP
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	CIP
	16b	Explanation of any interim analyses and stopping guidelines	CIP
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	eMaterials and methods
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)	eMaterials and methods
			Reported on page no.
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	eMaterials and methods

Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	eMaterials and methods
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)	eMaterials and methods
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	eMaterials and methods
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	6-7
	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group	6-7
	21c	How missing data were handled in the analysis	6-7
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc	6-7
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	5-6
	22b	For each group, losses and exclusions after randomisation, together with reasons	5
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	4
	23b	If relevant, why the trial ended or was stopped	/
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))	5, eMaterials and methods
	24b	Concomitant care received during the trial for each group	eTable 1
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	eTable 1
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis	5, 7

		● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	
Harms	27	All harms or unintended events in each group	10-11
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	eTable 1
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	13-14

eTable 1: CONSORT 2025 Statement e(8).

3

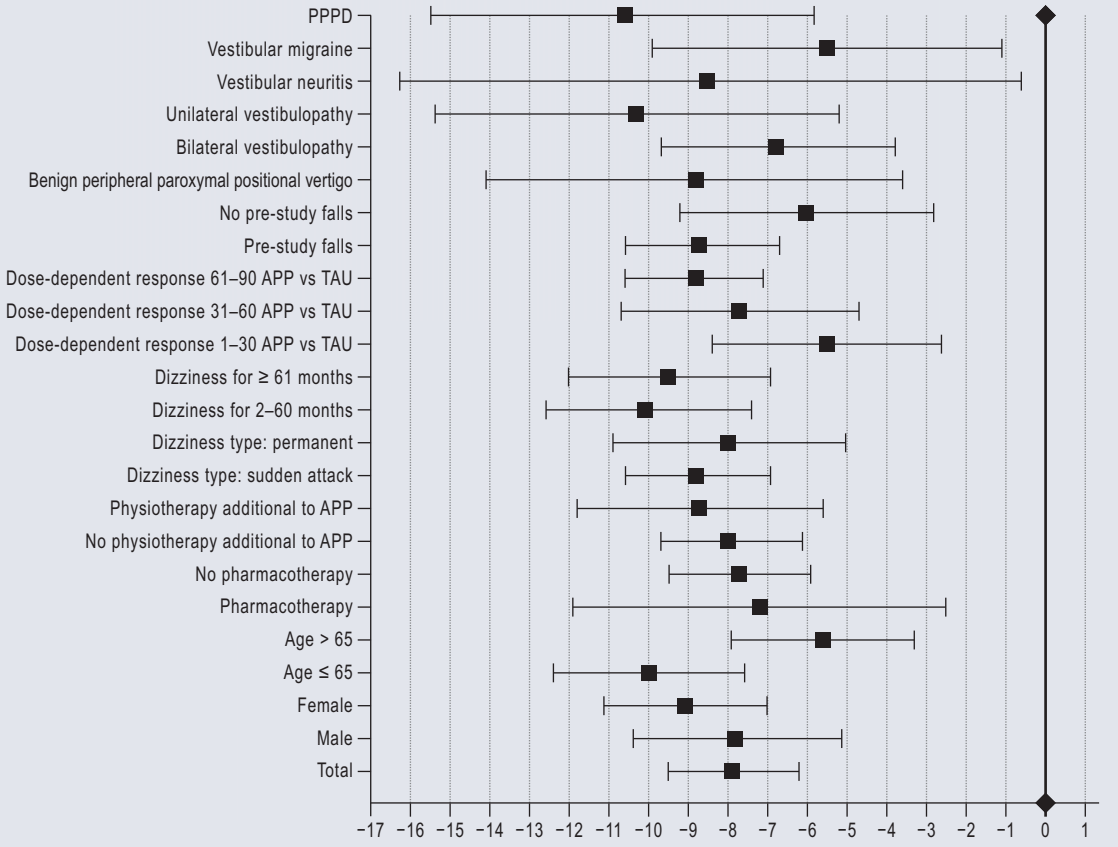
eTable 2

Demographic distribution

			APP (N = 106)	TAU (N = 106)	Total (N = 212)
Age (years)	Mean SD 25% quartile 75% quartile		61.63 14.55 54.0 72.0	64.68 16.25 56.5 76.0	63.16 15.46 55.0 75.0
	≤ 65	n (%)	63 (59.43)	42 (39.62)	105 (49.53)
	> 65		43 (40.57)	64 (60.38)	107 (50.47)
	18–30		4 (3.77)	6 (5.66)	10 (4.72)
	31–40		5 (4.72)	6 (5.66)	11 (5.19)
	41–50		12 (11.32)	6 (5.66)	18 (8.49)
	51–60		23 (21.70)	15 (14.15)	38 (17.92)
	61–70		28 (26.42)	22 (20.75)	50 (23.58)
	71–80		26 (24.53)	40 (37.74)	66 (31.13)
	81–90		8 (7.55)	10 (9.43)	18 (8.49)
	90+		0 (0.00)	1 (0.94)	1 (0.47)
Height (cm)	Mean SD 25% quartile 75% quartile		172.26 7.97 167.0 178.0	171.00 7.88 166.0 175.0	171.63 7.93 166.0 176.0
Weight (kg)	Mean SD 25% quartile 75% quartile		79.94 15.42 70.0 90.0	75.16 15.01 65.0 82.0	77.55 15.37 67.0 87.0
BMI (kg/m^2)	Mean SD 25% quartile 75% quartile		26.95 5.11 23.29 29.70	25.60 4.26 22.49 28.13	26.28 4.74 22.95 28.70
Sex	Male	n (%)	51 (48.11)	49 (46.23)	100 (47.17)
	Female		55 (51.89)	57 (53.77)	112 (52.83)
Neuroleptics/antipsychotics or antivertigo medication at baseline	n		0	0	0
Physiotherapy at baseline	n		0	0	0
Psycho-/psychiatric therapy at baseline	n		0	0	0

APP, Intervention with the digital health app; BMI, body mass index; mean, unadjusted arithmetic mean; N, sample size; n, number in category; SD, standard deviation; TAU, treatment as usual (physiotherapy)

eFigure



Exhaustive forest plot (cf. *Figure 4*) of APP treatment effect for *VSS*-sf-VER subgroups -(ITT):
Adjusted LS mean and 95% confidence intervals of app treatment effect determined by group comparison of T0-T3 changes. Dose-dependent response: days. Physiotherapy/pharmacotherapy: i.e., additional physiotherapy/pharmacotherapy. The black square indicates the mean value of the observed treatment effect. The horizontal line depicts the 95% CI. The vertical line (no-effect line) marks the point at which there is no treatment effect on the measured end point for the respective subgroup. With the exception of the subgroups female/male, all presented subgroup analyses were planned a priori. Selected subgroups of the forest plot are shown in *Figure 4*.
APP, Intervention with the digital health app; ITT, intention to treat; PPPD, persistent postural-perceptual dizziness; TAU, treatment as usual (physiotherapy); VSS-sf-VER, Vertigo Symptom Scale–Short Form vertigo

eTable 3

Treatment adherence in the two groups during the study period

	APP Days per week/12 weeks (N = 93)	TAU Number of sessions/12 weeks (N = 97)
Minimum	0.00	0.00
Mean	5.26	5.74
Median	7.00	6.00
Maximum	7.00	6.00
SD	2.56	1.13

Mean, Unadjusted arithmetic mean; SD, standard deviation
For the APP PP group, the average weekly usage of the app in days is indicated. For the physiotherapy PP group, the number of physiotherapy appointments kept over 12 weeks is shown.
In the physiotherapy group, 14/97 patients had more than six physiotherapy appointments (7–20) due to further out-of-study prescriptions; these cases also needed six sessions.
APP, Intervention with the digital health app; TAU, treatment as usual (physiotherapy)

eTable 4

Summary of mean adherence and compliance of the two PP groups

APP PP group	Physiotherapy PP group
Adherence (N = 93)	Adherence (N = 97)
n = 77 (82.8%)	n= 557/582 sessions (95.7%)
Compliance	Compliance
n = 80/93 patients (86.0%)	n = 88/95 patients (92.6%)

N = Sample size; n = number in category
Adherence: For the APP PP group the relative number of patients using the app at least once a week is shown. Mean adherence to the physiotherapy group is defined as the percentage of the number of sessions planned represented by the number of sessions attended (outliers above the theoretical maximum values in the groups were recoded to 7 for the APP group and 6 for the TAU group).
Compliance: In the APP group, compliance is the number of patients who performed exercises vs. the number who performed them as proposed by the APP. In the physiotherapy group, compliance is the number of physiotherapy patients vs. the number who really performed the exercises as proposed by the therapist.

eTable 5

Analysis of vertigo (VSS-sf-VER score, ITT) at each time point and in comparison with baseline

	Treatment	N	Mean	SD	Median	Range	LS mean difference		p-value (intergroup comparison)
							Estimate (SE)	[95% CI]	
Baseline	APP	106	19.12	4.38	18.00	12–32			
	TAU	106	15.98	3.86	15.00	12–30			
Week 02	APP	106	11.29	6.20	10.00	2–27			
	TAU	106	14.55	5.86	14.00	0–28			
Week 06	APP	106	7.79	5.93	6.00	0–25			
	TAU	106	12.38	5.44	12.00	0–24			
Week 12	APP	106	6.47	6.18	4.48	0–25			
	TAU	106	13.30	5.67	13.50	0–28			
Change from baseline [points]*1									
Week 02	APP	106	–7.83	6.50	–8.00	–27 to 11	–4.9 (0.8)	[–6.5; –3.3]	< 0.0001
	TAU	106	–1.43	5.36	–1.00	–19 to 11			
Week 06	APP	106	–11.33	7.02	–12.00	–30 to 9	–5.6 (0.8)	[–7.2; –4.0]	< 0.0001
	TAU	106	–3.60	5.27	–4.00	–18 to 9			
Week 12	APP	106	–12.65	7.29	–13.36	–31 to 9	–7.9 (0.9)	[–9.5; –6.2]	< 0.0001
	TAU	106	–2.68	5.39	–2.00	–19 to 14			
	Cohen's d for group difference in change from baseline to week 12						d = 1.55		

*1 Post-baseline values minus baseline values
LS means and p-values from ANCOVA with group and baseline value as covariate (LS, least square)
APP, Intervention with the digital health app; Mean, unadjusted arithmetic mean; SD, standard deviation; SE, standard error; TAU, treatment as usual (physiotherapy); VSS-sf-VER, Vertigo Symptom Subscale-Short Form vertigo
The changes from baseline values are also shown in the Table in the body of the article.

eTable 6

Diagnoses of the study participants

Diagnosis	APP (N = 106)	TAU (N = 106)	Total (N = 212)
	n (%)		
Acute vestibular syndrome	1 (0.94)	2 (1.89)	3 (1.42)
Senile vertigo, presbyvertigo*	12 (11.32)	10 (9.43)	22 (10.37)
Bilateral vestibulopathy	18 (16.98)	28 (26.41)	46 (21.69)
Benign paroxysmal positional vertigo (BPPV),	18 (16.98)	16 (15.09)	34 (16.03)
Superior canal dehiscence	1 (0.94)	0 (0)	1 (0.47)
Unilateral vestibulopathy	16 (15.09)	15 (14.15)	31 (14.62)
Functional vertigo, persistent postural-perceptual dizziness (PPPD), phobic vertigo, chronic vestibular syndrome, and vestibular syndrome (as secondary diagnosis)	13 (12.26)	16 (15.09)	29 (13.67)
Sudden hearing loss with vertigo (acute idiopathic sensorineural hearing loss with vestibular involvement)	1 (0.94)	1 (0.94)	2 (0.94)
Idiopathic vertigo	3 (2.83)	13 (12.26)	16 (7.55)
Cholesteatoma	0 (0)	0 (0)	0 (0)
Labyrinthitis	1 (0.94)	0 (0)	1 (0.47)
Menière's disease	5 (4.72)	7 (6.60)	12 (5.66)
Vestibular neuritis	13 (12.26)	10 (9.43)	23 (10.84)
Toxic vestibulopathy	1 (0.94)	1 (0.94)	2 (0.94)
Trauma	1 (0.94)	2 (1.87)	3 (1.42)
Tumors of skull base and cerebellopontine angle, acoustic neuroma	1 (0.94)	0 (0)	1 (0.47)
Vestibular migraine	18 (16.98)	9 (8.49)	27 (12.73)
Vestibular paroxysmia	0 (0)	2 (1.87)	2 (0.94)

N = Sample size, n = number in category. The sum n is higher than the population because patients could be assigned more than one diagnosis by physicians. PPPD was a secondary diagnosis. All patients suffering from PPPD had a further diagnosis as main diagnosis. Patients with vestibular migraine revealed the typical migraine symptomatology in addition to objective findings of peripheral vestibulopathy.

*Patients with bilateral vestibulopathy (caloric underexcitability) aged 60 years and older.
APP, Intervention with the digital health app; TAU, treatment as usual (physiotherapy)