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Glaucoma rehabilitation with action video games and exercise: study protocol of an active-controlled trial (GRADE)

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ABSTRACT

Introduction Glaucoma is the second leading cause of moderate to severe visual impairment worldwide, primarily affecting peripheral vision and increasing the risk of falls due to impaired balance and mobility. While traditional physical training (PT) is used for fall prevention, its effectiveness may be limited by low patient engagement. Action video games (AVGs) may offer a more engaging alternative for improving balance and mobility in individuals with glaucoma.

Methods and analysis This prospective, two-arm, single-blind, active-control trial will involve 56 patients with glaucoma with moderate to severe peripheral field loss and intact cognitive function, who have not previously undergone balance training. Participants will be randomly assigned in a 1:1 ratio to either a physically interactive action video-game training (AVG) group or a conventional PT group. The AVG group will use a Nintendo Switch gaming station for 20 sessions of 45 min each, conducted two to three sessions per week over 8 weeks. These sessions will involve standing game exercises using game controllers or body sensors, focusing on muscle stretching and strengthening, balance improvement and fitness. The PT group will engage in traditional PT for the same duration and frequency. The primary outcome is the change in mobility function after 20 sessions, measured by the narrow path walking test. Secondary outcomes include balance function (modified Clinical Test of Sensory Interaction and Balance, motor control test, landing balance test, five-time sit-to-stand test and time up and go test), visual cognition (reaction time test and useful field of view test) and patient-reported outcomes (validated questionnaires). Exploratory outcomes include fall frequency, fear of falling, visual function and serum brain-derived neurotrophic factor levels (one of the biomarkers related to exercise). Assessments will occur at seven time points: baseline (T1), after 10 sessions (T2), after 20 sessions (T3), 1-month post-training (T4) and 3, 6 and 9 months after all training sessions (T5–T7).

Ethics and dissemination The human ethics approval was obtained from the respective ethics board of the Hong Kong Polytechnic University (ID: HSEARS20210722001). The study protocol will conform to the principles of the Declaration of Helsinki. Results will be disseminated through peer-reviewed journals and conferences.

Trial registration number NCT06000865.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study incorporates a comprehensive range of outcome measures, providing a holistic assessment of the intervention's impact.
⇒ The two-arm, single-blind, active-controlled trial ensures robust comparisons between action video game training and physical training, minimising bias and increasing the reliability of findings.
⇒ Follow-up assessments at multiple time points allow for the evaluation of long-term effects on balance, mobility and quality of life.
⇒ Exclusion of participants with mild glaucoma may limit the generalisability of the results to patients with less severe conditions.
⇒ The absence of a no-treatment group makes it difficult to determine the interventions' effectiveness relative to non-treatment.

INTRODUCTION

Glaucoma affects approximately 64.3 million people worldwide and accounts for 11% of visual impairment among adults in Hong Kong.[1] This disease causes gradual and irreversible damage to the visual field, initially affecting peripheral vision and potentially progressing to central vision loss.[2] As optic nerve damage from glaucoma is currently irreversible, patients often experience a progressive and debilitating loss of peripheral vision, increasing their risk of collisions and falls[3 4] along with reduced balance function, mobility function[5] and, in some cases, impaired cognition.[6] To mitigate the risk of falls, patients with glaucoma are three times more likely to limit their activities compared with their sighted peers, which further reduces their physical fitness and quality of life.[7–9] Therefore, identifying sustainable and accessible interventions to improve mobility and reduce fall risk is crucial.

Traditional physical training (PT) interventions, such as the Otago Exercise Programme,[10] the Alexander technique,[11] Tai Chi[12] and yoga[13] have shown promise in improving physical condition among visually impaired patients. For instance, Tai Chi has been shown to improve knee

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proprioception and balance control,[12] while structured exercise programmes have significantly improved mobility and balance function.[14] Multimodal exercises like the Otago Exercise Programme[15] and yoga therapy have been found to enhance postural control and stability by improving somatosensory and vestibular responses in visually impaired participants.[13] Additionally, the Alexander technique has demonstrated improvements in mobility function and a trend towards reducing falls.[11 16]

Building on these successes, innovative approaches like action video game training (AVGT) are emerging as effective tools for enhancing balance function in older adults.[17–19] AVGT may have advantages over traditional physical therapy due to its ability to integrate real-time feedback, cognitive stimulation and dynamic motor challenges within an engaging and task-oriented framework. Unlike traditional rehabilitation, which often relies on repetitive exercises in controlled settings and may fail to fully engage patients or adapt to individual progress, AVGT requires rapid and accurate actions while switching between focused and distributed attention. Common platforms for these games include Xbox 360, Nintendo Wii, virtual reality-based games and computer-based video games. Exergames, which include PT components, improve muscle strength,[20] balance[19] and gait[21] in healthy older adults. Studies have shown that Wii Fit training and similar programmes significantly improve balance function in healthy adults.[18 22–25] Despite these promising findings, the effects of AVGT on mobility and balance in older adults with glaucoma have not yet been investigated.

Reduced visual cognition is significantly associated with decreased mobility performance in individuals with glaucoma,[26–28] which is linked to reduced quality of life.[28–30] Previous studies suggest that AVGT could improve visual cognition.[31–33] Compared with traditional physical exercise, AVGT increases cognitive engagement during the training process and provides real-time feedback, which is crucial for posture correction. We hypothesise that AVGT could improve mobility, balance, visual cognition and quality of life in patients with glaucoma, yielding superior training outcomes compared with conventional PT alone.

Objectives

Our two-arm, single-blind, active-controlled trial aims to:

1. Determine whether interventions designed to improve mobility function in patients with glaucoma can enhance their mobility, balance, visual cognition and quality of life, while reducing the fear of falling.
2. Assess whether AVGT provides greater benefits than traditional PT alone for patients with glaucoma.

This study is a two-arm, single-blind, active-controlled trial with 1:1 allocation, where participants will be randomly assigned to either the AVGT group or the PT group. Allocation will consider four factors: age, gender, exercise level and visual field severity. The protocol follows the Standard Protocol Items: Recommendations for Interventional Trials checklist.[34]

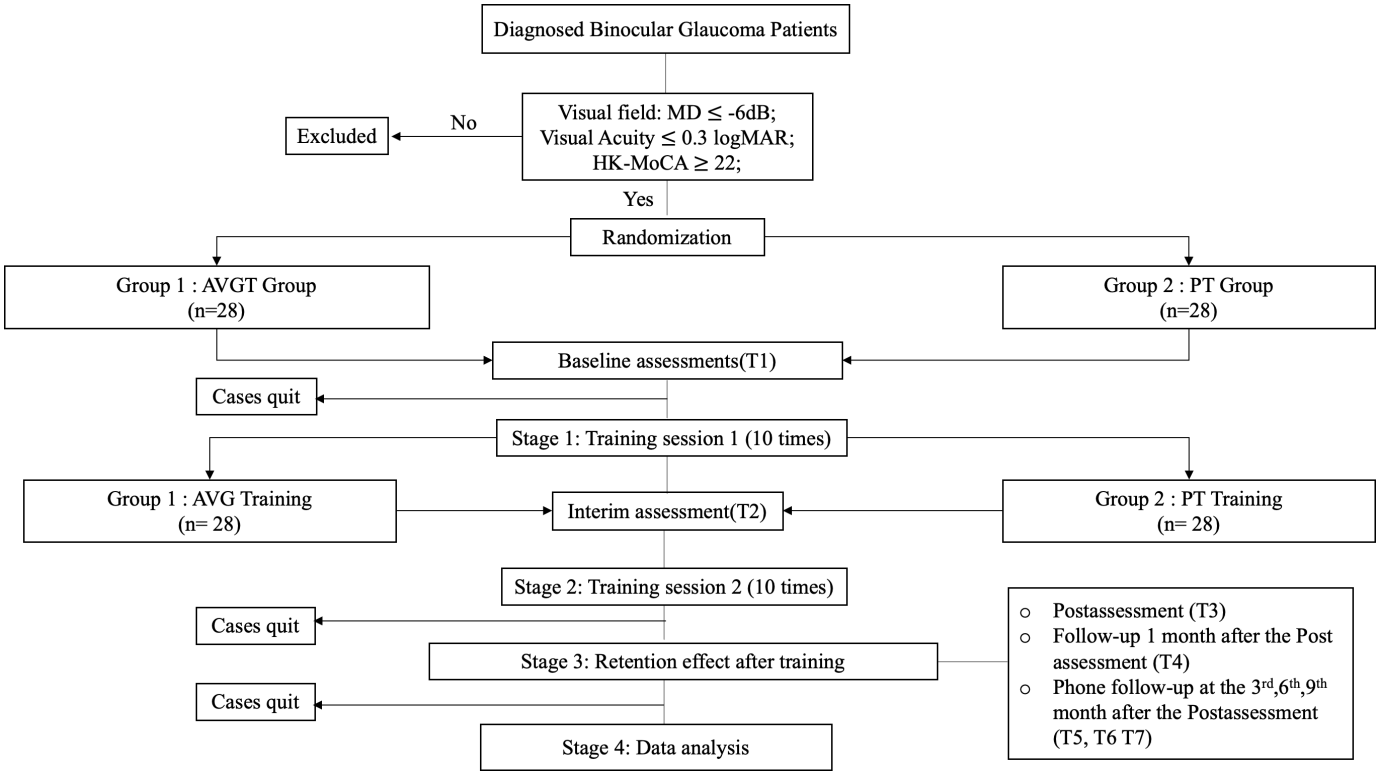

Figure 1 Flow chart of the whole study. AVGT, action video game training; HK-MoCA, Montreal Cognitive Assessment-Hong Kong version; MD, mean deviation; PT, physical training.

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METHODS AND ANALYSIS

Participants

Figure 1 provides a consort diagram of the planned flow of participants for this study. The trial will be conducted at a research centre within the Hong Kong Polytechnic University, chosen for its established optometry expertise and its capacity to recruit and manage a diverse patient population. Participants will be recruited through local ophthalmology clinics, hospitals, community centres and online platforms to ensure a broad and representative sample. Interested individuals will undergo a preliminary assessment, including a review of medical history and visual and cognitive evaluations, to confirm eligibility. All assessments will be conducted at the Hong Kong Polytechnic University, which is equipped with state-of-the-art facilities, enabling comprehensive assessments and interventions as outlined in the study protocol.

Eligibility criteria

Eligibility will be initially assessed through a phone screening that reviews medical history, medication use, current eye conditions and overall health. Volunteers who pass this screening will undergo comprehensive assessments of ocular, cognitive and physical functions to determine study eligibility based on predefined criteria. Participants aged 55–75 years are chosen due to the higher prevalence of glaucoma in this age group and the need to tailor interventions to their specific needs.

Inclusion criteria

1. Age between 55 and 75 years.
2. Diagnosis of primary open-angle or normal-tension glaucoma with relative scotoma in both eyes.[35]
3. Humphrey Field Analyzer visual field loss (mean deviation of ≤−6 dB) using the 24–2 testing protocol for both eyes.
4. Best-corrected distance visual acuity of 6/12 (equivalent to 0.3 logMAR) or better.
5. Cognitive functional score of 22 or above in the Montreal Cognitive Assessment-Hong Kong version.

Exclusion criteria

1. Presence of ocular diseases other than glaucoma, such as age-related macular degeneration, diabetic retinopathy or moderate to severe cataract.
2. Severe medical issues, including self-reported neurological conditions (eg, brain surgery, brain tumour and peripheral neuropathy) or cognitive disorders (eg, diagnosed dementia or cognitive impairment).
3. Physical impairments or limitations that restrict independent walking.
4. Self-reported or medically diagnosed vestibular/cerebellar dysfunction, history of vertigo or severe hearing loss.
5. Use of medications for any neurological conditions or psychiatric drugs (eg, sedative, hypnotic) that might interfere with motor control.
6. Currently participating in any physical or balance training programmes.
7. History of frequent falls, defined as more than three falls in the past 6 months.

Consent plan

Trained investigators will obtain informed consent from participants, providing detailed written information about the study, including its purpose and procedures. Participants will have time to ask questions before consenting, with the option to withdraw at any time. Consent for data use will cover study procedures, analysis and publication. An optional term will document consent for biological specimens, with any risks clearly outlined (online supplemental material 1).

Interventions

This study will compare two intervention approaches aimed at enhancing fitness, muscle strength and balance. Both groups will follow a similar schedule and structure, ensuring consistency in intervention delivery while exploring different methods to achieve these goals. Each participant will be involved for 48 weeks, including an 8-week intervention period and a 40-week unsupervised follow-up period. After eligibility screening, consent and baseline measurements, participants will be randomly assigned to either the AVG or PT group. Both groups will undergo a 4-week intervention, followed by an interim test, another 4-week intervention and post-tests at 1, 3, 6 and 9 months. During the 40-week follow-up, participants will report outcomes periodically without additional interventions.

AVG intervention

This study employs the Nintendo Ring Fit Adventure game (NRFA; Nintendo, Kyoto, Japan) as the AVGT intervention. NRFA, an exergame released in 2019, has been shown to improve balance, muscle strength, gait and reduce falls in older adults.[36–38] It uses a ring-shaped controller and a leg sensor to track movements.

Participants will engage in 45 min sessions over an 8-week period, following a 2-3-3-2 weekly schedule. Exercises, such as ‘whack-a-mole’, ‘squat jump’ and ‘inner thigh’, will be tailored for muscle stretching and strengthening, with immediate feedback. The selected exercises and games will be carefully curated based on recommendations from a physical trainer and a physiotherapist. Each session includes a 10 min warm-up, 30 min of aerobic and resistance exercises and a 5 min cool-down. An unmasked researcher will ensure the safety and efficacy. Specific video games are enumerated in figure 2.

PT intervention

The comparison group’s PT sessions will be led by a professional coach, mirroring the AVGT schedule. This programme will target overall fitness, muscle strength and balance, focusing on lower-body exercises. The coach will provide instructions and feedback to ensure proper

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Exercise routine	Name of games
10-minute Warm-up	Hip circles, dynamic stretching, arm circles….
30-minute exercise: 1.Jogging 2. Core exercise 3.Lower limb strengthening exercise 4. Balance exercise	**Exercise list A:** Side Step: 28 reps Knee Lift: 34 reps Squat: 14 reps Overhead Squat: 14 reps Seated Forward Press: 14 reps Knee Lift Combo: 20 reps Thigh Press: 14 reps Hip Lift:14 reps Plank: 20 reps Ring Raise Combo: 34 reps **Exercise list B(Game list):** Jogging in forest: 2 min Whack-a-mole: Primary level Break the boxes: Primary level Climb: Primary level Balance Walk:Primary level Squat Jump: Primary level Hand-drawn billet: Primary level Inner Thigh Knight: Primary level Coin Mercedes: Primary level
5-minute cool down	Dynamic stretching, arm circles….

Figure 2 A schematic diagram of physically interactive action video games used in the study.

technique and motivation, aligning with the AVGT group's structure and goals.

Criteria for discontinuing or modifying allocated interventions

Interventions will be discontinued if participants withdraw voluntarily, experience adverse events (eg, severe medical conditions that pose a significant risk to participant health or safety) or have significant discomfort or distress that does not resolve with overnight rest. Decisions to discontinue will be made collaboratively with the participant, prioritising their well-being. In principle, the assigned interventions cannot be switched after training has started. If the intervention is discontinued, outcome measurements will no longer be collected, and the results will be recorded as missing data.

Strategies to improve adherence to interventions

Participants will receive detailed explanations about the intervention's benefits and the importance of consistent participation. Personalised support, regular communication and a supportive environment will be provided to maintain engagement and motivation.

Relevant concomitant care permitted or prohibited during the trial

Participants in both study groups will be asked not to engage in other AVG or PT programmes related to balance training. Medical treatment of glaucoma will continue as usual.

Provisions for post-trial care

To ensure transparency, participants will receive a summary of the trial results on completion. The research team will also be available to address any queries or concerns that may arise after the trial, ensuring participants feel supported as they transition out of the study.

Outcomes

Participants will have 20 training sessions, with assessments conducted at seven different time points. These assessments consist of a baseline test (T1), a test after completing 10 sessions of training (T2), a test after completing all training sessions (T3), a test 1 month after completing all training sessions (T4) and follow-up tests 3, 6 and 9 months after completing all training sessions (corresponding to T5, T6 and T7, respectively).

At baseline, participants' ocular health will be evaluated through several assessments: (1) visual acuity will be measured both monocularly and binocularly using the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart, with best-corrected refractive corrections and habitual spectacle corrections; (2) contrast sensitivity will be tested using the MARS Numerical Contrast Sensitivity at 50 cm (with appropriate near addition) and (3) retinal nerve fibre layer thickness (RNFL) will be assessed using Spectralis optical coherence tomography (OCT, Heidelberg Engineering, Heidelberg, Germany). Table 1 and figure 3 outline the

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Table 1 Time points for the study

		T1	T1–T2	T2	T2–T3	T3	T4	T5–T7
Enrolment:								
Eligibility screen	x							
Informed consent	x							
Group allocation								
Interventions:								
Action video game training			x		x			
Physical training			x		x			
Assessments:								
Baseline clinical characteristics		x						
Primary outcome:								
Narrow path walking test		x		x		x	x	
Secondary outcomes:		x		x		x	x	
Balance functions:								
modified Clinical Test of Sensory Interaction and Balance								
Dynamic balance measures:								
Motor control test								
Landing balance test								
Five times sit-to-stand test								
Time up and go test								
Cognitive functions:								
Reaction time								
Simple reaction test								
Choice reaction test								
Useful field of view								
Quality of life:								
Simplified Chinese version of the 10-item Perceived Stress Scale								
Patient Health Questionnaire								
Chinese version of the Low Vision Quality-of-Life Questionnaire								
Physical Activity Scale for the Elderly-Chinese version								
Exploratory outcomes:								
Fall frequency		x						x
Fear of falling questionnaire		x		x		x	x	x
Vessel structure		x				x	x	
Visual field		x		x		x	x	
Blood test		x				x		

outcomes that will be assessed repeatedly throughout the experiment.

Primary outcome measure

The primary outcome is mobility function, assessed using the narrow path walking test (NPWT)—a modified version of the time up and go test (TUGT). This test provides a comprehensive evaluation of strength, balance, gait and functional speed in a challenging environment. The primary outcome is measured at time point T3, with T2 and T4 serving as secondary time points.

The NPWT procedure mirrors the TUGT, where participants stand up from a 46 cm tall chair, walk 3 m at their normal walking speed along a narrow pathway, navigate around an obstacle, return and sit down (figure 3). The path consists of a 40×300 cm green mat with 24% Michelson contrast, divided into two narrow 20 cm-wide pathways to enhance the challenge. To ensure reliability and accuracy, the test will be repeated three times for each participant.

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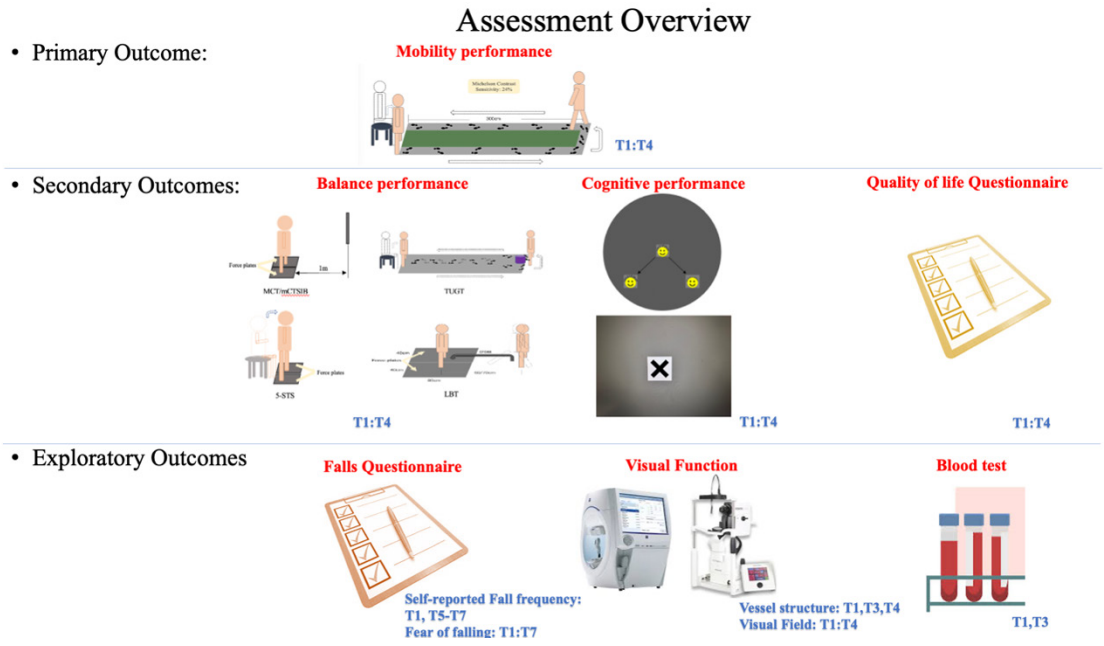

Figure 3 The overview of all outcome measures.

Mobility performance is assessed using the Vicon Motion System (Vicon Nexus V.2.9.1, Oxford, UK), which employs 39 reflective markers placed on the head, trunk and lower body according to the Vicon Plug-in whole body gait model. Key metrics analysed include completion time (s), spatial-temporal parameters[39] and turning performance (refer to table 2 for details). Additionally, the number of mistakes (ie, instances stepping outside the designated pathway)[40] is recorded. This parameter is crucial for identifying falling risk and balance function, with a higher number of mistakes indicating greater fall risk and poorer balance. The outcome measurement results will be collected and averaged from the three trials.

In our pilot study with 16 participants with glaucoma, the NPWT showed high intrarater repeatability and moderate to high correlations (Pearson correlation coefficient range: 0.539–0.937) with TUGT performance .[41] Completion time was identified as the most reliable parameter (r>0.90 and intraclass correlation of 0.994). Hence, completion time will be adopted as the primary outcome measure, while the other parameters will serve as secondary outcomes.

Secondary outcome measures

Secondary outcomes focus on balance, visual cognitive function and patient-reported outcome measures in patients with glaucoma.

The balance function will be assessed at four time points (T1–T4).

Static balance measures

Static balance will be assessed using a modified Clinical Test of Sensory Interaction and Balance with the Bertec Balance Advantage system (Bertec, Columbus, Ohio, USA) (figure 3).[42] Participants will stand on a force plate under the following four conditions:

1. Standing on a firm surface with eyes open.
2. Standing on a firm surface with eyes closed.
3. Standing on a foam surface with eyes open.
4. Standing on a foam surface with eyes closed.

Cognitive challenges are introduced through a visual task, which involves either fixation or searching for Chinese characters in conditions 1 and 2. For detailed information on the visual search task, refer to the study by Jia *et al*.[43] Each condition is repeated three times. The outcome measurement results will be collected and averaged from the three trials.

Outcome measures collected include the root mean square (RMS) sway of the centre of pressure (CoP) in the anterior-posterior (AP) and medial-lateral directions (ML, mm/s), visual task accuracy (%) and the Romberg quotient that assessed contribution of vision to balance in terms of changes in sway area data from eye closed to eye open (%) (table 2).

Dynamic balance measures

The dynamic balance function will be evaluated using the motor control test (MCT), the landing balance test (LBT), the five times sit-to-stand test (5-STS) and TUGT (figure 3). Outcome measures will be collected at four time points (T1–T4).

Motor control test

The MCT evaluates participants' automatic motor reflex responses to sudden forward or backward movements of a stable surface.[44] This test will be repeated three times. The outcome parameter results will be collected and averaged from the three trials. Outcome parameters include the RMS sway of CoP in both ML and AP directions (mm), the visual task accuracy (%) and the reaction latency to translation (ms) (table 2).

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Table 2 The overview of all the outcomes

Tests	Outcome variables	Definition
Primary outcome: mobility performance		
Narrow path walking test	Completion time	Mean completion time of three trials (main primary outcome measure)
	Spatial-temporal parameters of gait: ► Cadence (steps/min) ► Stride time (s) ► Stride length (m) ► Walking speed (m/s) ► Step width (m) ► Step length (m) ► Per cent preferred walking speed (%)	Cadence: mean number of steps/min of three trials Stride time: mean stride time of three trials Stride length: mean stride length of three trials Walking speed: mean walking speed of three trials Step width: mean step width of three trials Step length: mean step length of three trials Per cent preferred walking speed: walking speed/preferred walking speed×100%
	Dynamic balance in gait performance: ► Mistakes in one trial (a mistake is defined as the subject stepping outside the narrow path) ► The medio-lateral displacement of centre of mass	Mistakes in trials: mean mistakes made of three trials The medio-lateral displacement of centre of mass: mean centre of mass movement of three trials
	Turning performance: ► Turning time (s)	Mean time of finishing turning for three trials
Secondary outcomes		
Balance performance		
Modified Clinical Test of Sensory Interaction and Balance	Visual task accuracy	The correct rate during the task
	Medio-lateral root mean square sway	The mean sway of three trials in different conditions
	Anterior-posterior root mean square sway	The mean sway of three trials in different conditions
	Romberg quotient	The ratio of sway area with eyes closed to that with eyes open
Motor control test	Visual task accuracy	The correct rate during the task
	Latency	The mean latency of three trials in different conditions
	Medio-lateral root mean square sway	The mean sway of three trials in different conditions
	Anterior-posterior root mean square sway	The mean sway of three trials in different conditions
Landing balance test	Time to stabilisation	The mean time to stabilisation of three trials in different conditions
	Medio-lateral root mean square sway	The mean sway of three trials in different conditions
	Anterior-posterior root mean square sway	The mean sway of three trials in different conditions
	Sway area	The mean sway area of three trials in different conditions
Five times sit-to-stand test	Completion time	The total time of trial
	Centre of mass displacement	The total centre of mass displacement of trial
	Centre of mass velocity	The mean centre of mass velocity for anterior-posterior, medio-lateral directions of trial
	Peak extension joint moments	The peak extension joint moments of trial
Time up and go test	Completion time	The mean completion time of three trials
Visual-cognitive performance		
Reaction time test (simple reaction test, choice reaction test)	Reaction time	The mean reaction time for correct response of three trials
	Mistakes	The correct rate during the cognition test task of three trials
Useful field of view test	Duration time	The mean minimum exposure duration for achieving 75% accuracy for each subtest (stimulus identification, divided attention, selective attention)

Continued

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Table 2 Continued

Tests	Outcome variables	Definition
Patient-reported outcome measures		
Low Vision Quality-of-Life Questionnaire	Score	The total score of the questionnaire
Perceived Stress Scale-10	Score	The total score of the questionnaire
Patient Health Questionnaire-9	Score	The total score of the questionnaire
Physical Activity Scale for the Elderly-Chinese version	Score	The calculated score of the questionnaire following the questionnaire manual
Exploratory outcomes:		
Fall frequency	Falls per year	The falling times per year
Fear of falling questionnaire	Score	The total score of the questionnaire
Visual function		
Visual field performance	Visual field	The mean defect of visual field
Retinal vessel structure and density	Vessel density	The mean vessel density
Blood test	The level of BDNF	The mean level of BDNF

BDNF, brain-derived neurotrophic factor.

Landing balance test

The LBT is a modified jump-landing test that assesses dynamic balance.[45] Participants will stand 60 cm or 70 cm away from two Bertec force plates and use their dominant leg to step onto the plate, stabilising as quickly as possible. They will maintain their position on the force plate for 10 s. This test will be repeated five times. The outcome parameter results will be collected and averaged from the five trials. Outcome parameters will include the time to stabilisation (ms), RMS sway of the CoP in the AP and ML direction (mm) and total sway area (mm^2) (table 2).

Five times sit-to-stand test

The 5-STS assesses lower limb muscle strength, crucial for dynamic balance.[46] Participants will rise from a 43 cm high chair on hearing the cue 'start', placing both feet on a force plate while keeping their arms crossed over their chests, and then sit down as quickly as possible five times. Completion time (s) and kinematic parameters, including the CoP displacement (mm), velocity (mm/s) and peak extension joint moment (Nm/kg), will be recorded (table 2).

Time up and go test

The TUGT is a commonly used assessment for detecting the dynamic balance function for visually impaired adults,[26 29] where participants will stand up from a 46 cm tall chair, walk 3 m at their normal walking speed, navigate around an obstacle, return and sit down. In our study, we will use the TUGT completion trial time (s) to detect our participants' dynamic balance function. The test will be repeated three times to get a reliable completion time (table 2). The outcome measurement results will be collected and averaged from the three trials.

Visual-cognitive function

Outcome measures on visual-cognitive function will be collected at four time points (T1–T4).

Reaction time

The reaction time test consists of two parts: the simple reaction test (SRT) and the choice reaction test (CRT). Each part is repeated three times to calculate the average reaction time (table 2). The outcome measurement results will be collected and averaged from the three trials.

- SRT[47]: participants respond to a central stimulus by pressing a button. Reaction time (ms) will be recorded.
- CRT[48]: four squares are displayed horizontally on the screen, with the stimulus appearing randomly in one square. Participants must react to the stimulus's position as quickly as possible. Both reaction time (ms) and accuracy (%) will be recorded.

Useful field of view

The useful field of view (UFOV) test evaluates visual processing speed and attention, addressing visual challenges faced by older adults in everyday tasks such as reading and navigation.[49] The duration (ms) for each condition will be recorded (table 2). The UFOV test includes three conditions (figure 4):

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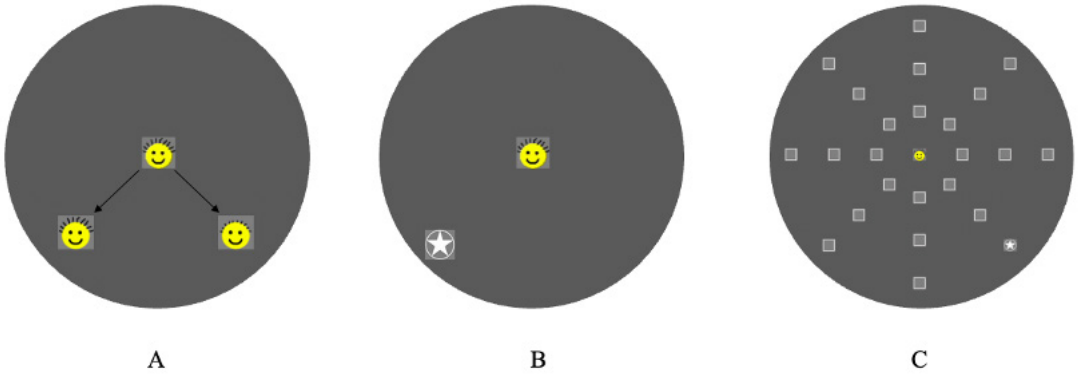

Figure 4 Schematic diagram of the useful field of view test. The central target is a smiley face with short or long hair, while the peripheral target is represented by white stars within a square. Distractors are depicted as squares. (A) Condition 1—visual processing speed is assessed by having participants recognise the central target stimulus. (B) Condition 2—divided attention requires participants to recognise both central and peripheral targets. (C) Condition 3—selective attention involves participants recognising both central and peripheral targets amid distractors.

- Stimulus identification: a central target is shown for 60 frames, followed by a 'white noise' screen. The display duration is adjusted using a 3-up/1-down adaptive staircase procedure to determine the threshold, concluding after eight reversals or 72 total trials.
- Divided attention: a central and a peripheral target appear simultaneously, with the peripheral target randomly positioned at one of eight meridian locations (0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°, 360°) at 20° from the centre. The presentation duration is adjusted as condition 1 to determine the threshold.
- Selective attention: this condition adds peripheral distractors to the central and peripheral targets. The procedure is similar to condition 2, with threshold measures collected for each participant.

Patient-reported outcome measures

This trial aims to enhance balance and mobility in patients with glaucoma. To evaluate the effectiveness of these interventions, four validated questionnaires will assess changes in quality of life, mental health, mobility function and physical activity. Outcome measures will be collected at four time points (T1–T4).

Chinese version of the Low Vision Quality-of-Life Questionnaire

This instrument assesses the impact of low vision on quality of life, focusing on challenges related to vision, lighting, mobility, psychological adjustment and daily activities. Participants are asked to rate the degree of difficulty from 'no difficulty' to 'extreme difficulty' they experience in various aspects of their daily lives due to low vision. Scores range from 25 to 125, with lower scores indicating greater difficulty.

Simplified Chinese version of the 10-item Perceived Stress Scale-10

This scale assesses perceived stress in Chinese-speaking communities, covering feelings of being overwhelmed, nervousness, anxiety, coping abilities and stress-related thoughts. Each item is rated from 0 ('never') to 4 ('very often'), with higher scores indicating greater levels of perceived stress.

Patient Health Questionnaire-9

The Patient Health Questionnaire-9 is a reliable tool for screening and assessing depression severity,[50] based on the nine symptoms outlined in the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition criteria. Scores range from 0 to 27, with higher scores indicating more severe depressive symptoms.

Physical Activity Scale for the Elderly-Chinese version

The Physical Activity Scale for the Elderly-Chinese version (PASE-C) assesses physical activity in older adults, focusing on low-intensity activities such as gardening, walking and light housework. PASE-C scores are computed by multiplying the time spent (hours/day over a 7-day period) and participation (yes or no) by activity-specific weights, with totals ranging from 0 to 500 or more. Higher scores reflect greater physical activity levels.

Exploratory outcome measures

Fall frequency

To assess the impact of the intervention on reducing fall incidents, participants will self-report the number of falls they experience at four time points (T1, T5–T7).

Fear of falling

The Chinese version of the Falls Efficacy Scale-International questionnaire will be used to evaluate the intervention's impact on participants' confidence and willingness to engage in daily activities. It has demonstrated good reliability and validity in assessing fear related to performing basic everyday activities among visually impaired individuals.[3] Participants will rate their concern about performing daily activities on a scale from 1 (not concerned) to 4 (very concerned). Higher scores indicate greater fear of falling, which may relate to balance issues. This measure will be administered at seven time points (T1–T7).

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Visual-related physiological functions

Exercise is known to enhance systemic circulation, which can include increased ocular blood flow[51] and levels of neurotrophic factors such as brain-derived neurotrophic factor,[51 52] potentially benefiting the visual capabilities. To determine whether the interventions can improve visual function and retinal circulation, visual field, vessel structure and vessel density were included.

Visual field performance

Visual field performance will be evaluated by the 24-2 Swedish Interactive Thresholding Algorithm full-threshold Humphrey visual field (Carl Zeiss Meditec, Dublin, California, USA). This measure will be administered at four time points (T1–T4).

Retinal vessel structure and density

OCT and optical coherence tomography angiography (OCTA) will scan the macular and optic nerves to explore structural changes. Measurements include macular thickness and RNFL using Heidelberg Spectralis OCT (Heidelberg Engineering, Heidelberg, Deutschland) and vessel density using the OCTA module. This measure will be administered at three time points (T1, T3 and T4).

Serum brain-derived neurotrophic factor

Blood samples will be collected before and after the training (T1 and T3). Approximately 5 mL of blood will be drawn, and serum plasma will be analysed by the ELISA method.[53] The 4-parameter logistic curve will be used to analyse the relationship between absorbance and analyte concentration, using Python for data insights.[54]

Satisfaction questionnaire

A satisfaction questionnaire will be administered after the training to evaluate the effectiveness of the training programme and identify areas for improvement. This questionnaire includes items from the physical activity enjoyment scale and a self-developed acceptability. Details of the satisfaction questionnaire are provided in online supplemental material 2.

An overview of all outcomes is reported in table 2.

Sample size

Due to the lack of studies on AVGT for glaucoma, sample size calculations are based on previous studies of video game training and traditional PT in healthy older adults, using G*Power (V.3.1).[55–57] Assuming a statistical power of 0.8, a significance level of 0.05, an average effect size of d=0.72 (derived from TUG after-trial time results) and a 10% attrition rate, the estimated minimum sample size is 56 participants. Participants will be recruited from multiple sources, including the optometry clinic at the Hong Kong Polytechnic University, Grantham Hospital, patients' self-help groups and private optometry and ophthalmology clinics through referrals. The recruitment period began in January 2023 and is expected to conclude in August 2025. To expand our reach, we also used advertisements on social media platforms, including Facebook and Google, as well as our project webpage. During recruitment, participants receive comprehensive information about the study. This includes the study timeline, a detailed explanation of all procedures, potential risks and the benefits of each intervention. This ensures participants are well-informed and can make decisions with a clear understanding of the study.

Assignment of interventions: allocation and blinding

An independent staff member will use a computerised minimisation randomisation algorithm to allocate participants to the AVG group or PT group. This approach ensures that the two groups are as similar as possible with respect to key factors, including age, gender, exercise level and glaucoma severity. Allocation concealment will be maintained using a centralised, password-protected system. Outcome assessors will be blinded to the intervention group, while participants and the staff member involved in the interventions will be aware of the assignments due to the active-control design. On confirming participant eligibility, the site investigator will access the randomisation system for intervention assignment. Unblinding will occur after the data lock. The study's statistician, who will be unblinded, will conduct outcome analyses according to the prespecified statistical analysis plan. Other study team members will gain access to the unblinded datasets after the analyses are completed.

Data collection and management

Team members receive comprehensive training covering recruitment, intervention procedures, assessment techniques and data management protocols. Initially, all data will be recorded on paper to ensure accuracy and completeness. Subsequently, these data will be uploaded to Research Electronic Data Capture (REDCap), a secure web application for managing research data. To protect personal information, all physical records, including personal data, will be stored in a locked filing cabinet with controlled key access, ensuring that only authorised personnel can access them. To promote participant retention and ensure complete follow-up, we will maintain engagement through regular communication, which may include phone calls, emails or text messages, depending on participant preference. We will offer flexible scheduling options for follow-up visits to accommodate participants' availability while still adhering to the study's follow-up schedule. Additionally, we will continue to conduct follow-up visits even if participants deviate from the intervention protocol, ensuring that we collect comprehensive data and maintain participant involvement throughout the study. To maintain high data quality, data will be reviewed promptly following each assessment. If any issues with data quality are identified, repeated measurements will be conducted. All outcome measures will be entered into a secure, password-protected computer system. De-identified data will be stored within a Microsoft Teams group and on a hard drive, both of which are accessible solely to research team members. Each participant will be assigned a unique identification number to facilitate the matching of their corresponding data files, ensuring confidentiality and efficient data management.

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Participant information will be anonymised using unique identifiers, ensuring that sensitive data are accessible only to authorised personnel. Strict measures will be taken to maintain confidentiality and protect participant privacy in any dissemination of trial results or publications. Following informed consent acquisition, blood specimens are obtained from participants via standard venipuncture. This procedure employs a sterile needle and syringe integrated with the Vacutainer collection system. Approximately 5 mL of blood is drawn from the antecubital vein and deposited into 5 mL Greiner Bio-One Vacuette tubes. The collected blood is then permitted to clot at ambient temperature for 30–60 min without disturbance. Subsequent centrifugation at 3000× *g* (4°C for 20 min) isolates serum from cellular components. The clarified serum is meticulously aliquoted into prelabelled 1 mL Eppendorf tubes. To ensure sample stability, the aliquots are frozen and archived at −30°C pending further analysis.

Statistical methods for primary and secondary outcomes

The primary analysis will be quantitative, using SPSS software with a significance level of 0.05. The histograms and the probability-probability plots will be used to describe the baseline data for the two groups. The Shapiro-Wilk test will be used to check the normality of the data. Continuous variables will be summarised as means with SD or medians with IQRs, depending on the normality of the data. Discrete variables will be described using frequencies or composition ratios. For skewed numerical data, we will apply appropriate transformations to assess whether the data meet the normality assumption. The baseline data will be displayed in the table.

The primary outcome will be assessed by measuring differences in NPWT completion time from baseline, indicating the effectiveness of interventions. A baseline-adjusted ANCOVA analysis will be used to compare the groups while controlling for baseline values. The group with the greatest reduction in completion time will demonstrate the strongest intervention impact. Changes in completion time across four time points (baseline, interim 1, postintervention and 1-month postintervention) will illustrate the dose-response relationship and recovery duration. To account for intersubject variability, a linear mixed model was used with intervention type and time points as fixed effects, and baseline MD value as a covariate.

To address potential attrition and missing data due to participant drop-out, sensitivity analyses will be conducted using multiple imputation methods, specifically the fully conditional specification method. This approach allows for the imputation of missing data for multiple variables with different distributions. These analyses will assess the robustness of the primary analysis results against potential attrition bias and missing data, ensuring that conclusions are not unduly influenced by the potential non-random nature of missing data.

The analyses of secondary and exploratory outcomes will follow a similar approach to that of the primary outcome. A detailed statistical analysis plan for these outcomes is being developed and will be reviewed by the steering committee before data analysis begins.

Interim analyses

Not applicable. All data will be analysed at the end of the experiment.

Methods for additional analyses (eg, subgroup analyses)

The primary end point analysis will be complemented by exploratory subgroup analyses. These analyses will examine factors such as exercise frequency (ranging from never to often) and severity of glaucoma based on baseline assessments. The findings will be presented in a comprehensive table and a visual forest plot, including effect size estimators ($\eta 2$) and 95% CIs. The table will also provide the number of subjects in each subgroup and the corresponding p values. Furthermore, t-tests and correlational analysis will be used to examine average differences between groups.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data

To manage protocol non-adherence, both per-protocol and intention-to-treat analyses will be conducted to evaluate its impact on study outcomes. Sensitivity analyses will also be performed to assess the robustness of the findings in the presence of non-adherence. For handling missing data, multiple imputation techniques will be employed to account for incomplete or absent data points, ensuring that the statistical analyses are based on the most comprehensive dataset available.

Plans to give access to the full protocol, participant-level data and statistical code

The full study protocol is publicly accessible on the ClinicalTrials website (https://clinicaltrials.gov.cNCT06000865). The datasets analysed and the statistical code used in the analysis are available from the corresponding author on reasonable request.

ETHICS AND DISSEMINATION

Composition of the coordinating centre and trial steering committee

The coordinating centre is School of Optometry at the Hong Kong Polytechnic University. The project steering committee consists of core research team members: Professor Allen Cheong, Professor Ben Thompson and Professor Stanley Winser. Their duties include managing participant randomisation, ensuring both assessors remain blinded and safeguarding the confidentiality of participants' personal information.

Composition of the data monitoring committee, its role and reporting structure

A senior researcher, independent of the study, will regularly monitor the study. This includes reviewing documents, regulatory compliance, enrolment processes, participant data, safety and protocol deviations. After the

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review, the monitor will report findings that need resolution, which the investigative team will address.

Adverse event reporting and harms

Adverse events will be recorded in the REDCap and managed according to the Hong Kong Polytechnic University clinical trials emergency guidelines.

Frequency and plans for auditing trial conduct

The principal investigator conducts bi-weekly monitoring and auditing of trial conduct and data collection. Researchers involved in different aspects of the study shall report their progress and challenges faced to the principal investigator. Additionally, a data monitor is assigned with assessing the integrity and quality of data every 2 weeks, providing feedback to the principal investigator.

Plans for communicating important protocol amendments to relevant parties (eg, trial participants, ethical committees)

Important protocol amendments will be promptly communicated to the investigators and steering committee, with detailed documentation of the rationale and potential impact. Proposed changes will be submitted to the ethics committee for approval if necessary. Updated protocols will be distributed promptly, and additional training will be provided to study investigators as needed. Any alterations to the participant experience will initiate a new consent process.

Ethics approval

The current project has been approved by the Hong Kong Polytechnic University Institutional Review Board. The reference number is HSEARS20210722001.

Dissemination plans

The findings of this study will be presented at research conferences and seminars as part of the continuing professional development and published in peer-reviewed scientific journals. Participants will be provided with a copy of the main findings.

DISCUSSION

The Grading of Recommendations, Assessment, Development and Evaluations study is pioneering in its investigation of AVGT as a means to enhance mobility, balance and visual-cognitive functions in older adults with glaucoma. This research addresses a critical gap in current treatment options, as traditional interventions often fail to fully engage patients or provide real-time feedback necessary for optimal improvement. By enhancing these areas, the study also aims to reduce the fear of falling and improve the overall quality of life for patients. AVGT offers cognitive engagement and real-time feedback, potentially offering superior outcomes compared with traditional physical exercise. This study shall assess whether AVGT can be a supplementary or alternative intervention to conventional PT for fall prevention. Given the increasing prevalence of glaucoma in the ageing population, innovative approaches like AVGT are urgently needed to address the multifaceted challenges faced by these patients.

However, the study faces limitations, such as challenges in recruiting subjects with bilateral moderate to severe-stage glaucoma. Future research shall include individuals with mild glaucoma. The personalised nature of the physical exercise training may introduce variability, which could lead to bias. To mitigate this, the exercise regimen will align closely with AVGT objectives, focusing on muscle strength and balance. Additionally, the lack of a no-treatment group may limit the ability to draw definitive conclusions about the intervention's effectiveness, as it prevents a direct comparison with untreated participants. Addressing this in future studies could enhance the validity of the findings.

Trial status

Ongoing.

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Contributors AMYC conceived the research question. YH, VS, MC, SW and AMYC conceptualised the study design. AYH and IL collected the research data. AYH wrote the manuscript with feedback from BT, SW and AMYC. All authors gave final approval for the version to be published. AMYC is the guarantor. ChatGPT 4o-mini: during the preparation of this manuscript, the authors used ChatGPT to improve the language. After using this tool to edit the grammar, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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Correction: *'Glaucoma rehabilitation with action video games and exercise: study protocol of an active-controlled trial (GRADE)'*

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This article has been corrected since it was published online. The order of authors has been updated from 'Yihong Peng, Allen Ming Yan Cheong, Benjamin Thompson, Stanley Winser, Iris Lau, Venus Suen, Man Cheung' to 'Peng Yihong, Benjamin Thompson, Stanley Winser, Iris Lau, Venus Suen, Man Cheung, Allen Ming Yan Cheong'.

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