RCT protocol for driving performance in people with Parkinson’s using autonomous in-vehicle technologies

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ARTICLE INFO

Keywords:
Parkinson’s disease
Driving intervention
RCT
Study protocol
Automated in-vehicle technologies
Driver rehabilitation specialist
Kinematic data

ABSTRACT

Introduction: Driving is an essential facilitator of independence, community participation, and quality of life. Drivers with Parkinson’s Disease (PD) make more driving errors and fail on-road evaluations more than healthy controls. In-vehicle technologies may mitigate PD-related driving impairments and associated driving errors. Establishing a rigorous study protocol will increase the internal validity and the transparency of the scientific work.

Methods: We present a protocol to assess the efficacy of autonomous in-vehicle technologies (Level 1) on the driving performance of drivers with PD via a randomized crossover design with random allocation. Drivers with a PD diagnosis based on established clinical criteria (N = 105), referred by neurologists, are exposed to two driving conditions (technology activated or not) on a standardized road course as they drove a 2019 Toyota Camry. The researchers collected demographic, clinical, on-road data observational and kinematic, and video data to understand several primary outcome variables, i.e., number of speeding, lane maintenance, signaling, and total driving errors.

Discussion: The protocol may enhance participant adherence, decrease attrition, provide early and accurate identification of eligible participants, ensure data integrity, and improve the study flow. One limitation is that the protocol may change due to unforeseen circumstances and assumptions upon implementation. A strength is that the protocol ensures the study team executes the planned research in a systematic and consistent way.

Following, adapting, and refining the protocol will enhance the scientific investigation to quantify the nuances of driving among those with PD in the era of automated in-vehicle technologies.

Trial registration: ClinicalTrials.gov NCT04660500.

1. INTRODUCTION

Parkinson’s disease (PD) is a neurodegenerative disorder estimated to affect 12.9 million people globally by 2040 [1]. The four cardinal symptoms of PD include resting tremor, rigidity, bradykinesia, and postural instability [2], all of which may impair driver fitness. Additionally, individuals with PD can experience visual and cognitive impairments. Which also affect driving performance. Specifically, these impairments include deficits in binocular acuity and contrast sensitivity [3–5], visual scanning and processing speed [5–7]; set-shifting and cognitive flexibility [4,7–9] and psychomotor speed (reaction time, slow walking, and fine motor movements) [5,6,10,11].

Such performance deficits can significantly impair fitness to drive and increase the risk of drivers making driving errors compared to healthy controls, in addition to impacting their fitness to drive abilities, and driving safety on the road [4,12–17]. Drivers with PD make more errors in speeding, lane exceedances, and signaling than healthy controls [4,13,18,19], which are predictive of poorer performance in a driving simulator and predictive of failing an on-road evaluation [13, 18]. Therefore, PD affects the sustainability of safe driving [19]. Especi-}

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https://doi.org/10.1016/j.conctc.2022.100954
Received 14 February 2022; Received in revised form 26 May 2022; Accepted 23 June 2022
Available online 28 June 2022
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obey rules and signs of the road while controlling the vehicle and staying within the flow of traffic.

In Western societies, driving is the primary mode of transportation and an essential facilitator of independence, community participation, and quality of life [20,21]—and the same holds true for drivers diagnosed with PD. As mentioned above, drivers with PD make more driving errors and have an increased failure rate when completing on-road assessments compared to healthy controls. Technology may be one way to mitigate driving errors and to keep drivers with PD on the road, longer, and safer. A scoping review among older adults using in-vehicle technologies indicates that drivers are making fewer driving errors, execute the driving task with little effort, and experience less stress when driving with in-vehicle technologies [22]. Therefore, in-vehicle technologies may hold plausible opportunities for people with PD and may enhance their driving safety, convenience, and/or comfort, but remains greatly underexplored in the PD and driving literature.

Driving involves operational, tactical, and strategic control [23,24]. Operational driving maneuvers occur when a swift reaction of the driver is necessary to avoid a potential obstacle or adverse condition. Drivers with PD are often aware of their diminished driving skills at the operational level such as inability to swerve in a timely fashion to avoid an obstacle in the road. Tactical driving maneuvers include routine driving functions, such as negotiating traffic infrastructure via appropriate speeding up, stopping or turning. People with PD may experience an impairment in tactical maneuvers—e.g., difficulty judging and accepting an appropriate gap when turning against oncoming traffic. Drivers with PD are also likely to experience impairments in strategic driving maneuvers, such as experiencing challenges with decisions related to trip planning before or during the drive, which may result in wayfinding problems. Therefore, in-vehicle technologies, possibly assisting in the operational (e.g., automatic emergency braking), tactical (e.g., automatic cruise control), and/or strategic (e.g., activated global positioning system), hold plausible opportunities for drivers with PD. Moreover, the availability of in-vehicle technology in standard vehicles, including advanced driver assistance systems (ADAS) and in-vehicle information systems (IVIS), has increased exponentially throughout the last decade. Many ADAS and IVIS features are standardized into vehicles manufactured after 2018 [25]. Because drivers with PD make significantly more errors in speeding, lane exceedances, and signaling [4,13,18,19], in-vehicle technologies may offset such driving errors while potentially enhancing their driving safety.

1.1. Benefit of ADAS and IVIS

Advanced driver assistance systems are integrated systems that interact with drivers to assist them with tactical and operational vehicle maneuvers in high-risk situations [26]. Because speed and lane position are compromised in people with PD [11,13], Adaptive Cruise Control (ACC) may automatically adjust the speed through deceleration or acceleration while maintaining the vehicle’s headway time from lead vehicles, preventing driving errors and mitigating potential crash risk. Therefore, using this technology, a driver with PD may overcome challenges in processing speed to maintain a safe headway. Lane Keeping Assist (LKA) compensates for steering deficits of drivers with PD by helping the driver stay within the lane. As such, technology-based interventions, such as ACC or LKA, may offer functionality to mitigate driving errors conducted under high-risk driving tasks (e.g., emergency braking) or daily driving. Technologies hold plausible opportunities for people with PD—specifically to enhance their driving safety.

In-vehicle information systems (IVIS) are technologies that provide information related to traffic conditions, navigation, weather conditions, or hazard alerts to support drivers in their decision-making. These IVIS may mitigate and compensate PD-related deficits related to driving. For example, blind-spot detection provides auditory and/or visual cues to help alert the driver of vehicles approaching the adjacent lane and mitigate the cognitive dual-task, i.e., checking the blind spot while scanning the forward driving scene demand. Likewise, Lane Departure Warning (LDW) systems use visual and/or auditory or haptic stimuli to alert the drivers that they are drifting out of the lane. The alerted driver can then correct the error and re-center the vehicle appropriately with these prompts. In summary, ADAS and IVIS may be helpful for drivers with PD to overcome speeding, lane exceedances, and signaling errors and/or mitigate those errors [26].

1.2. Rationale and significance

The prevalence of PD is expected to double over the next two decades to affect 12.9 million people worldwide [1]. Drivers with PD make significantly more errors in speeding, lane exceedances, and signaling [4,13,18,19], which are predictive of poorer performance in a driving simulator [27,28] and failing on-road evaluations [13,18]. A technology-based intervention to extend driver fitness, modify driver behavior, mitigate the PD-related factors affecting driving, and decrease driving errors, is now a plausible reality—but has not been examined in an on-road vehicle and real-world traffic situations.

1.3. Objective

The objective of this study is to assess the efficacy of autonomous in-vehicle technologies (Level 1, SAE: ADAS and IVIS) on drivers with PD when driving with and without activation of the technologies in an on-road intervention using a test vehicle (Toyota Camry 2019).

1.4. Hypothesis

The hypothesis is that people with PD who drive with vs. without activation of the autonomous in-vehicle technology will significantly reduce the total number of driving errors in a standardized road-course. We also assume that drivers with PD will demonstrate fewer speeding, lane exceedances, and signaling errors when driving with autonomous in-vehicle technology. Specifically, ADAS may decrease driving errors related to speeding (via the Adaptive Cruise Control) and lane exceedances (via the Lane-Keeping Assist). Likewise, IVIS may decrease driving errors pertaining to lane exceedances (via the Lane Departure Warning system) and signaling/unsafe lane changes (via the Blind Spot Detection).

2. METHODS

2.1. Design

The Institutional Review Board approved the study with full board review (IRB2020002321). This study is an efficacy study using a randomized crossover design. Participants experience two driving conditions: one with the technologies activated and another with the technologies deactivated. The order of technology (with vs. without activated technology) is randomly allocated to control for order effects of the road sections. Participants serve as their own controls.

2.2. Study setting

Participant intake and clinical assessments are conducted at the University of Florida (UF) Norman Fixel Institute for Neurological Diseases. The driving intervention took place on a standardized road section in Gainesville, Florida [see Fig. 1 [29]].

2.3. Participant recruitment

Movement disorder neurologists identify potential participants during a routine clinic visit at the Norman Fixel Institute for Neurological Disease and local Parkinson disease support groups. Subsequently a trained research assistant follows up with the referral and conducts a
Calculations were conducted based on the following assumptions: The driving errors of people with PD has a Pearson’s correlation of 0.5 between the two conditions, i.e., driving vs. without in-vehicle technologies; the effect size (Cohen’s $d = 0.443$) was determined by the mean number of total on-road driving errors made by drivers with PD in a previous on-road study (31.99, SD = 22.03) minus the mean number of on-road driving errors (24.08, SD = 12.38) made by healthy controls, $\Delta = 7.91$ [13]; with a standard deviation (SD) for the change score assuming 0.5 correlation = 22.01. With a sample size of 105 drivers, the study has 95.4% power to detect a 25% decrease of on-road total driving errors among drivers with PD while using in-vehicle technologies in the activated vs. deactivated state, with $\alpha = 0.05$. The power calculation is based on a two-sided independent-sample $t$-test because participants acted as their own controls.

2.5. Inclusion and exclusion criteria

Participants are included if they have: clinically probable PD as defined by the Movement Disorders Society [30]; are adults (age range from 35 to 85) with mild or moderate disease severity based on evaluation motor scores and modified Hoehn and Yahr; on a stable medication regimen for 4 weeks; Montreal cognitive assessment total score $> 20$; demonstrate proof of a valid driver’s license; have driven within the last six months; live independently in the community; and are proficient in reading and speaking English.

Participants are excluded if they: have a concurrent neurological condition (e.g., stroke, seizures; dementia); severe psychiatric condition(s) (e.g., psychoses/significant anxiety); physical condition(s) (e.g., missing limbs or legal blindness); adverse functional effects from the use of psychotropic medications; severe, unpredictable motor fluctuations; or severe sleep difficulties.

2.6. Intervention

The proposed intervention is driving with the technologies (i.e., ACC, BSM, LDW, and LKA) and without. The intervention is based on the postulation that in-vehicle technologies may compensate for driving deficits and reduce driving errors. Driver rehabilitation specialists control the technologies features for on/off conditions and evaluate the driving errors, as participants drive the standardized course.

2.7. Allocation

Eligible participants are randomly allocated to drive two congruent drives (one with and without in-vehicle technologies) on a standard route in Gainesville, Florida. The order of the drives is based on simple randomization using R version 3.4.0 [31]. Such random allocation ensures that each subject is driving the standardized road course, under both conditions (technologies activated vs. deactivated), in a balanced order.

2.8. Outcome

The primary outcome variable is the total number of driving errors. These driving errors are recorded by (certified) driver rehabilitation specialists by type and number of speeding errors (5 miles per hour under or over the posted speed limit), lane maintenance errors (wide or encroach), and signaling errors (activate turn signal yes/no) on a standardized driving error sheet. Additionally, driving error kinematic data are also collected via two mounted cameras (i.e., two GoPros, three USB cameras) and a Freematics ONE + telemetry kit—to provide objective and contextual data.

2.9. Participant timeline and procedure

After obtaining informed consent the participants undergo a battery of clinical assessments which include a visual acuity test via the Snellen chart [32] and Optec 2500 Visual Analyzer [33]. Participants are required to meet the Florida state requirement of 20/70 in either eye or both eyes together with or without corrective lenses. If one eye is blind or 20/200 or worse, then the other eye needs to be 20/40 or better; and the participant must have a field of vision 130° or more. Participants complete a cognitive screening via the Montreal Cognitive Assessment (MoCA) and must score $> 20$ [34,35]. Eligible participants also complete the Demographic Questionnaire, Movement Disorder Society-Sponsored Revision of the Unified Parkinson’s Disease Rating Scale, Part 3 (MDS-UPDRS Part 3) [36], Modified Hoehn and Yahr disease severity scale [37], Impulsive Behavior Scale (UPPS-P) (including Urgency,
Premeditation (lack of), Perseverance (lack of), Sensation Seeking, Positive Urgency) [38], Technology Readiness Index [39], the Autonomous Vehicle User Perception Survey [40,41] and the Parkinson’s Disease Questionnaire-39 [42].

The (certified) driver rehabilitation specialist orients participants to the test vehicle, a Toyota Camry XLE 2019 with Level 1 in-vehicle technologies [43], and check for participant proficiency in managing the vehicle’s controls e.g., steering, brake, and gas pedals. Each participant completes a standardized 7-min acclimation drive in the Fixel Institute parking lot for familiarization with the vehicle using the in-vehicle technologies.

After completing the acclimation drive, participants drive the standardized road course.

2.10. Standardized road course

The route begins in a parking lot, leading to an urban/downtown area, and a highway, with mild to moderate traffic, while encountering other road users [44]. The road course includes 29 controlled intersections (i.e., traffic signs or signals), 107 uncontrolled intersections, 11 left turns, and 11 right turns, as indicated in Fig. 1. The speed limits vary between 10 and 70 mph on two-lane and four-lane roadways and a divided highway. The road course is 26.5 miles in driving distance and takes approximately 50–65 min to drive, depending on the traffic flow.

3. DATA collection

3.1. Clinical assessments

Movement disorder neurologists complete motor assessments including the MDS-UPDRS Part 3 and modified H&Y. A trained graduate assistant and the (certified) rehabilitation specialist collect participant characteristics and the scores of the clinical tests.

3.2. On-road data

(a) Data collected by the (certified) Driver Rehabilitation Specialists

The (certified) driver rehabilitation specialists document the errors on a standardized error sheet indicated in the Appendix, modeled after [44]: the error sheet is divided into three zones, the parking lot, suburban roadways, and a highway — and provided an area for the driver rehabilitation specialist to log the driving errors. Additional information such as weather conditions and experience with technology is recorded. Three Yes/No questions indicate the use of the in-vehicle technology during the drives.

Speeding errors are recorded as over and under-speeding (five mph above or below the posted speed limit). Lane maintenance errors are classified as encroaching or wide errors. During straight driving, a wide error refers to the vehicle crossing the lane marking towards the road shoulder, while encroaching refers to the vehicle crossing the lane marking towards the oncoming traffic. While making a turn, encroaching errors occur when the driver positioned the vehicle to cross over the lane marking nearest the inside of the turn [44,45]. Wide errors occur when the driver positions the vehicle to cross over the lane marking towards the outside of the turn [44,45]. Signaling errors refer to making a turn or a lane change without activating or deactivating the turn signal. Signaling errors are recorded as a dichotomous yes/no variable and are assessed 100 feet before and after turning or changing lanes.

(b) Video data

When the ADAS and IVIS features are activated, icons and alerts are captured on video. The timing, duration, and count of these activations are automatically detected using a computer vision model via a software program that takes images and videos as input and returns the probability that pre-determined objects (e.g., interface icons represent the different ADAS and IVIS) are present. Computer vision models are trained to detect the activation of LDW, LKA, and ACC. A separate computer vision model is trained to detect the number of BSM alerts. Finally, the Freematics One+ vehicle telemetry kit collects the vehicle’s speed and GPS location (latitude and longitude). The vehicle instrumentation includes a Freematics One+, two GoPro Hero 7 Silver, three USB cameras (two ELP wide-angle cameras recording at 720p resolution and one Logitech C922 webcam recording at 1080p resolution), and a Garmin 55W dashcam to capture on-road video data. A recording program (Open Broadcaster Software) collects and stores video data from the three USB cameras in the Dell Precision laptop mounted on the vehicle’s back seat. Kinematic data (i.e., vehicle’s speed and GPS location) is collected from the secure digital card inserted in the Freematics One+. The video data from the Garmin dash-camera and Go Pros are collected from the secure digital cards, respectively, immediately following the drivers’ completion.

4. DATA management and analysis

4.1. Clinical assessment

The research assistant reviews data with the driver rehabilitation specialist, the trained graduate assistant, and enters data into a secure, password-protected RedCap system [46]. The Regulatory Knowledge and Research Support program of the Clinical and Translational Science Institute (CTSI) at UF fully supports this software. To access the system, all participants will be assigned a unique participant ID number and all data will be labeled and stored by the corresponding participant ID number. Data containing HIPAA identifiers will only be accessible to project team members who have been approved by the IRB. Additionally, data can be viewed by a generic text file editor and/or Microsoft Excel (.exl), Portable Document Format (.pdf), and Rich Text Format (.rtf).

4.2. On road data

(a) Data collected by the (certified) driver rehabilitation specialists

The (certified) driver rehabilitation specialists collect the data via a standardized on-road error sheet (in Appendix). Data is imported into the university’s RedCap system.

(b) Video data

Raw video and telemetry data is stored on a password protected server for data processing. The human factors engineer extracts, manages and processes the computer vision data via Python and R scripts to generate the number of ADAS and IVIS activations during each segment of the drive. Kinematic data is extracted, cleaned and processed via R scripts to determine the different segments of the drive (suburban vs. highway; ADAS and IVIS activated vs. not activated) and the associated speed limits, using the GPS coordinates, resulting in a final count of over and under-speeding events during each segment of the drive. All processed data are entered into RedCap.

4.3. Statistical methods

(a) Driving Errors. Inferential Analyses:

For the main outcome variable (total number of driving errors), normally distributed, we will use the appropriate statistical analysis which may be non-parametric (data not normally distributed and assumptions of normality not met) or parametric (data normally distributed and assumptions of normality met). ANOVA will be performed to compare if differences exist for the PD Drivers (N = 105; younger vs.
older; mild vs. moderate disease severity) who drove under the two conditions (autonomous in-vehicle technology vs. no autonomous in-vehicle technology). Model selection and model diagnostics will be considered. Then, the final model will indicate which covariates (e.g., age, gender, education, cognitive status, motor performance, and experience with autonomous vehicle technologies) have significant effects on the outcome variable(s). It will also show the intervention effect while controlling for the different PD groups and the independent variables. Next, we will perform data analysis for describing the time course of driving errors, and for comparing such patterns between the PD drivers (younger vs. older; mild vs. moderate disease severity) [47]. In this analysis, log-linear modeling with mixed-effects or generalized estimating equations will be considered for accommodating the within-subject data correlation. From this analysis, we can identify the difference in driving performance errors between the PD Drivers, under the two driving conditions (technology de/activated). The team will use log-linear models to regress the significant factors based on the total age, gender, education, cognitive status, motor performance, and the two driving conditions (technology (de)activated). The team will use difference in driving performance errors between the PD Drivers, under two conditions (autonomous in-vehicle technology vs. no autonomous in-vehicle technology). Model selection and model diagnostics will, again, be considered. The final model will indicate which covariates (e.g., age, gender, education, cognitive status, motor performance) have significant effects on the longitudinal control variables. It will also show the intervention effect while controlling the different PD groups and the independent variables.

4.4. Possible discomforts and risks

The clinical tests pose no anticipated risks or discomfort beyond those present in everyday activities. On-road driving is the riskiest activity, but similar to everyday driving, with a small chance for a crash, or near miss-with IRB approved protocol to manage such an event. This study may also include risks that are unknown at this time. During the study, the research team will notify participants of new information on study risks that may become available and affect a person’s decision to remain in the study.

4.5. Possible benefits

Participants learn about technology features common in vehicles manufactured after 2018, and how such technologies may offset PR and driving-related deficits. Drivers with PD, caregivers, clinicians, and other stakeholders may be educated about the benefits of in-vehicle technologies to support the driving performance of people with PD. Participants who complete the on-road session are reimbursed $30.00 for their participation.

5. DISCUSSION

The objective of this publication is to document the protocol to assess the efficacy of autonomous in-vehicle technologies (Level 1, SAE: ADAS and IVIS) on the driving performance of drivers with PD, under two conditions, i.e., with (out) the technologies on-road in a test-vehicle.

To our knowledge, this is one of the first in-vehicle technology intervention studies targeting people with Parkinson’s disease. This study is an important steppingstone towards conducting effectiveness studies, across sites, and in different geographic locations.

Making study protocols publicly available, this study may lay the foundation, for follow-up work for other investigators. Publishing study protocols will also inform the scientific community of what studies are conducted, which helps avoid duplication (Ohtake & Childs, 2014). Establishing, following, and revising the study protocol as needed, may contribute to the integrity, or internal validity of a study. For example, a well-documented protocol ensures that the study personnel perform their duties within the scope of the study and the parameters of the protocol, which may be mitigating or preventing implicit or explicit biases. Finally, publishing a study protocol has an inherent benefit of securing beneficence and non-maleficence for participants, while also describing ethical conduct of research particularly pertaining to privacy, security, confidentiality and right to choose, that will benefit the participants when protocol is executed accordingly [49].

A weakness is that study protocols may change due to unforeseen circumstances, or erroneous assumptions, upon implementation. The research team has experienced both. First, the impact of COVID-19 was not anticipated at the time when the study protocol was written. As such the research team had to pivot, during the implementation of the study protocol, to adopt strategies related to recruitment, intervention, and safety of the participants and project personnel. Moreover, the team had to develop and enhance safety protocols according to the CDC, state, and university guidelines. Second, although we assume that the on-road video data will contribute to a richer understanding of the driving context and driving errors made, much trial and error was necessary to position the cameras in such a way that “glare” from the road was mitigated. Although the team experienced challenges in the early stages of study implementation, the protocol allowed us to make adaptations for successful continuation with the study.

The strengths of this protocol are many-fold. For example, we are using comprehensive clinical assessments, broad and representative patient population, state-of-the-art equipment, and cutting-edge technology, to identify and quantify, fitness to drive issues in people with mild to moderate PD. Second, we are using a hybrid approach of collecting subjective evaluator-based data and objective kinematic-based data. Data may be compared and contrasted to help with standardizing data collection procedures and to outline best practices. Third, having a well-described protocol enables the study team to execute the research plan, but also to make changes as needed, without diverting from the overall procedures or objectives of the study. Fourth, the published study protocol may serve as a model for other researchers interested in this field—and advance the timeline, research methods, and internal validity for future similar studies. Fifth, the composition of the study team (neurologists, human factor engineers, rehabilitation scientist, driver rehabilitation scientist, driver rehabilitation specialists, and graduate students in training), is such that all aspects of understanding the nuances of drivers with PD, particularly in the era of automated vehicle technology, are considered, discussed, understood, and disseminated.

Overall, this protocol lays the foundation to understand a significant
quality of life and safety issue in drivers with PD. If the results are in favor of driving with in-vehicle technologies, people with PD may extend their driving lifetime as well as stay engaged in community life and societal roles. Such results will position this research team to disseminate first-time knowledge, shed light on the automated in-vehicle technology adoption practices, and reveal the perceptions, facilitators, and barriers of driving with such in-vehicle technologies—when the study team stays true to the protocol and/or makes swift adjustments when necessary.

Research question

What is the study protocol to assess the efficacy of in-vehicle technologies on the driving performance of people with Parkinson’s disease?

Funding and acknowledgements

This RCT is funded by the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR, award number 90IFRE0035). NIDILRR had no role in the design or execution of the protocol.

The authors acknowledge the Institute for Driving, Activity, Participation, and Technology (I-DAPT), Human systems Engineering Lab, and the Norman Fixel Institute for Neurological Diseases at the University of Florida, which provided the infrastructure and support for this study.

Author contributions

The authors confirm contribution to the paper as follows: Sherrilene Classen: Conceptualization, Methodology, Participant recruitment, Writing-draft preparation, Writing-reviewing and editing, Supervision. Yuan Li: Data collection, Participant recruitment and enrollment, Writing-draft preparation, Writing-reviewing and editing. Wayne Giang: Conceptualization, Methodology, Data collection, Investigation, Writing-reviewing and editing. Adolfo Ramirez-Zamora: Conceptualization, Methodology, Participant recruitment, Data collection, Writing-reviewing and editing. Beth Gibson: Data collection. Jason Rogers: Data collection, Editing. Adolfo Ramirez-Zamora: Conceptualization, Methodology, Participant recruitment, Data collection, Investigation, Writing-reviewing and editing. All authors reviewed and approved the final manuscript of the protocol.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.conctc.2022.100954.

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