ORIGINAL RESEARCH

Adverse Events in Older Adults at Risk for Dementia During Remote Physical Exercise and Cognitive Training

Karla J. Faig, MAHSR[1], Aidan E. Steeves, BA PSCY[1], Chris A. McGibbon, PhD[2,3], Molly A. Gallibois, MSCKin[2], Alanna K. Bohnsack, MPH[1], Josée S. Haché, MD[4], Grant A. Handrigan, PhD[5], Carole C. Tranchant, PhD[6], Andrew M. Sexton, BScEE[3], Samantha M. Knill[1], Pamela G. Jarrett, MD, FRCPC[1,7]

[1]Horizon Health Network, Saint John, NB; [2]Faculty of Kinesiology, University of New Brunswick, Fredericton, NB; [3]Institute of Biomedical Engineering, University of New Brunswick, Fredericton, NB; [4]Vitalité Health Network, Moncton, NB; [5]School of Kinesiology and Recreation, Faculty of Health Sciences and Community Services, Université de Moncton, Moncton, NB; [6]School of Food Science, Nutrition and Family Studies, Faculty of Health Sciences and Community Services, Université de Moncton, Moncton, NB; [7]Dalhousie Medicine New Brunswick, Dalhousie University, Halifax, NS

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ABSTRACT

Background

SYNchronizing Exercises, Remedies in GaIt and Cognition @Home (SYNERGIC@Home/SYNERGIE~Chez soi) is a home-based, double-blind, randomized controlled trial. Sixty community dwelling older adults (aged 60–90 years), living in New Brunswick, Canada, who were at risk of dementia participated remotely using secure videoconferencing. Participants underwent 16 weeks (three sessions/week) of cognitive and physical interventions. This research aimed to determine the frequency, severity, and relationship of adverse events (AEs) that occurred during the physical and cognitive intervention phase of the SYNERGIC@Home study. This study addressed a critical question: Whether AEs occurring during a remote exercise and cognitive intervention for older adults at risk of dementia can be managed safely and effectively to optimize participation.

Methods

All AEs were recorded, including type, severity, and their relatedness to the intervention. Intervention modifications due to AEs were also recorded.

Results

Participant's mean age was 69.5 years (SD=6.47), 76.7% were female, and 58.4% were living in suburban or urban communities. A total of 88 AEs affected 42 (70.0%) participants. Most AEs (71.6%) were unrelated to the intervention, and 69.3% were classified as mild, with musculoskeletal issues being the most common AE (39.8%). One unrelated serious AE was recorded. Modifications to the physical intervention were made for 31 participants, and two discontinued due to unrelated medical issues.

Conclusions

When delivered remotely, physical and cognitive interventions resulted in no serious related AEs and the few related, mostly mild AEs, were safely managed through modifications to the physical interventions.

Key words: adverse events, remote intervention, dementia prevention, cognitive training, physical exercise, older adults, randomized controlled trial

INTRODUCTION

As the population ages, the personal and financial burden of caring for individuals with Alzheimer's disease and related dementia (ADRD) grows.(1) There are known risk factors for dementia, and multi-domain interventions have been shown to be effective in delaying the onset or decreasing the severity of dementia.(2-4) Some studies, such as Synchronizing Exercises, Remedies in Gait and Cognition at Home (SYNERGIC@Home), have offered remotely delivered physical and cognitive interventions to older adults at risk for ADRD.(5) While this increases accessibility by removing the barriers of travel and expanding reach,(6) it also comes with potential risks. Understanding adverse events (AEs) experienced by older adults in dementia risk reduction initiatives such as SYNERGIC@Home is essential for ensuring safety and improving intervention delivery.

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human

Use (ICH) glossary of terms 2023 defines adverse events as any unfavourable medical occurrence in a trial participant, and the AE does not always have a causal relationship to treatment.[7] The reporting of AEs in research is an area that has fallen under scrutiny, prompting an extension of the CONSORT statement in 2004 (revised in 2022) aimed at improving reporting.[8,9] Despite these recommendations, incomplete reporting of AEs in research remains a problem in both published and unpublished studies.[10,11] Furthermore, a systematic and standardized reporting of AEs is missing from many studies.[12]

Research involving older adults engaged in physical exercise interventions has also provided limited reporting of AEs.[13] Fyfe *et al*. examined the feasibility and safety of delivering remote physical exercise interventions for older adults during the COVID-19 pandemic.[14] In their study, AEs were self-reported by participants in a diary that was returned weekly to the research team for review. Huang *et al*. reported that no AEs occurred in their two-month home-based exercise intervention with older adults living with cognitive impairment.[15] Two recent systematic reviews and meta-analyses also report low rates of AEs for the remote delivery of physical interventions in older adults, with falls being reported infrequently as related to the invention.[16,17] In addition, many of the studies reviewed did not report AEs as part of their results. In a systematic review and meta-analysis by Neimeijer *et al*. involving 773 randomized controlled trials of exercise therapy delivered in person, 97.4% (n = 753) reported adverse events (AEs), 48.9% (n = 378) of which were serious AEs, while 48.5% (n = 375) reported non-serious AEs.[12] Their findings, based on a sample where older adults were the largest participant group, demonstrated that there was no increased risk of serious AEs from participation, although there was an increase in the risk of non-serious AEs. They also comment on the inadequate reporting of AEs, suggesting that systematic collection of AEs is rare.[12]

Given the paucity of systematic and standardized reporting of AEs, this research aimed to determine the frequency, severity, and relationship of the AEs that occurred during the physical and cognitive intervention phase of SYNERGIC@Home. Moreover, it describes the modifications required to the intervention because of the AEs. In doing so, we addressed the following research question: Can the AEs that occur during a remote exercise and cognitive intervention for older adults at risk of dementia be managed safely and effectively to optimize participation?

METHODS

SYNERGIC@Home/SYNERGIE~Chez soi (NCT04997681) is a double-blind, randomized controlled trial (RCT) evaluating the feasibility of remotely delivering a home-based intervention program of physical exercise and cognitive training for improving cognitive and physical functioning in older adults at risk for ADRD.[5] The research protocol was approved by four institutional Research Ethics Boards (Horizon Health Network; Vitalité Health Network; Université de Moncton; University of New Brunswick) and informed consent was obtained in writing from all participants. Participants were randomly assigned to one of four intervention arms consisting of: combined exercise (aerobic and resistance) + cognitive training (NEUROPEAK™); combined exercise + control cognitive training (web searching); control exercise (balance and toning) + cognitive training; and control exercise + control cognitive training.

The study manager, research manager, and the research assistant (RA) delivering the interventions knew the study arm allocation; however, the rest of the research personnel, including the study physician overseeing the monitoring of the AEs, were blinded to the participant's arm during the trial. RAs received training on how to maintain blinding with both the participant during interventions and with the AE reporting so as to not disclose the study arm allocation. All participants received some form of physical exercise (balance and toning in the physical control arms) and some online intervention (web searching in the cognitive control arms) to facilitate blinding.

Participants completed all assessments and interventions in their own home using videoconferencing technology to connect with study staff (Zoom for Healthcare™). Physical and cognitive interventions were completed three times per week for 16 weeks, with sessions lasting approximately 90 minutes. The physical exercise sessions were supervised by a certified personal trainer assigned to each participant.

The ICH definition of AEs was used for the SYNERGIC@ Home study.[7] AEs were classified by the reviewing study physician for their severity, as well as their relationship to the intervention. The study physician, who was blinded to group allocation, had generic descriptions of participant activities which allowed them to ascertain relatedness to the intervention. All intervention arms included a component of exercise. For severity, mild was used when there was no disruption of normal daily activity, moderate when there was an effect to normal daily activity, and severe when the AE caused the inability to work or perform normal activity. The relationship was labelled as: not related, unlikely, possible, probable, or definite. Standard descriptions for AE relationship were used for each category and provided to the staff reviewing the AE. Only AEs reported during the 16-week physical and cognitive intervention stage were used for this analysis.

A Standardized Operating Procedure (SOP) for reporting AEs was developed for SYNERGIC@Home, as well as a standardized Adverse Event (AE) Report Form. All study staff who had contact with participants received training on detecting and reporting AEs. Part of this training included removing any information that would indicate which arm of the study that the participant had been allocated to in their reporting of AEs. At the beginning of each remote intervention session, the research assistant (RA) asked the participant about any changes in health or issues that might have arisen since the last session. Any changes were reported as AEs. In addition, any AEs discovered or arising during an intervention session were reported.

As per the SOP, any suspected serious AE was reported immediately by telephone to the research manager and study physician for follow-up and reporting following institutional guidelines. For the remaining AEs, the AE Report Form was completed and securely e-mailed, with no personal identifying data, to the study physician, research manager, and research coordinator (RC) who supervised the intervention staff. For non-serious adverse events, the study physician reviewed the AE report within 24–48 hours, documented any follow-up instructions or required modifications to the intervention, and emailed the response back to the RA, RC, and research manager. The AEs were monitored by the study physician until they were resolved, or until the participant completed the intervention phase of the study. The AE Form continued to be used in an asynchronous manner to communicate between the study physician and the RA overseeing the intervention until such time that the AE was resolved. In this way, modifications to the interventions, as well as any medical interventions, could be clearly tracked and documented.

All AE Forms were communicated electronically and were stored on a secure SharePoint site at the lead institution in a de-identified manner. A summary report of all AEs was reported to the Data Safety and Monitoring Committee that met three times per year during the study period. AE reporting occurred during the study to the Research Ethics Boards that approved this study.

The data used in this study was collected as part of the SYNERGIC@Home RCT[5] and included: age, biological sex, language of participation (English or French), residence location (urban/suburban/rural), level of education, daily step count, One Minute Sit-to-Stand Test score,[18] Lawton-Brody Instrumental Activities of Daily Living Scale,[19] Functional Activities Questionnaire,[20] Montreal Cognitive Assessment Version 8.1 Audiovisual scores (MoCA),[21] Short Test of Functional Health Literacy in Adults scores (STOFHLA),[22] and Clinical Frailty Scale (CFS)[23] scores.

For the primary outcome, AEs were analyzed using a chi-square cross-tabulation analysis between AE severity and AE relation to trial, to test the hypothesis that there was a relationship between AE severity and being in the trial. The secondary outcome, to test the null hypothesis that treatment assignment was unrelated to the frequency of AEs, was done using a chi-square test of independence to assess whether adverse events were equally distributed across treatment arms. Descriptive statistics were used to describe the study sample with means and standard deviations (SDs) calculated.

RESULTS

Description of Population

Participants randomized to an intervention arm for SYNERGIC@Home (N=60) had a mean age of 69.5 years (SD=6.47) and were predominantly female (76.7%). Overall, participants tended to be physically inactive, with a mean daily step count of 3,602 (range=301–14,855 steps). Participants were taking an average of 3.6 (SD=2.76) prescription medications, and 48.3% were taking at least one cardiovascular medication. The mean number of dementia risk factors in this sample was 4.6, with the most frequently reported being: poor sleep (75.0%), poor diet (71.7%), first degree relative with dementia (68.3%), and physical inactivity (66.7%) There was no statistically significant difference (p>.05) between any demographic or any other characteristics between the treatment arms (Table 1).

The mean MoCA score was 25.6 (SD=6.24). Scores on the MoCA range from 0–30, with higher scores indicating less cognitive impairment.[24] Health literacy scores, assessed using the Short Test of Functional Health Literacy in Adults (STOFHLA),[22] were high, with a mean of 95.7 (SD=6.24). Scores between 75 and 100 indicate adequate health literacy. The mean Clinical Frailty Scale (CFS)[23] score among participants (n=59) was 2.4 (SD=0.9), indicating a level consistent with being well to managing well.[25] Individuals with a CFS score of 2 have no active disease symptoms and often exercise or are very active occasionally, whereas those with a CFS score of 3 have well-controlled medical problems, but are not regularly active beyond routine walking.[23]

Adverse Events

There were 88 related and unrelated adverse events reported in 70.0% (42/60) of the participants. For those experiencing an AE, the average number of AEs per participant was 2.1 events over 16 weeks. Of the 88 AEs, 69.3% (n=61) were classified as mild, 29.5% (n=26) as moderate, and 1.1% (n=1) as severe across all intervention arms.

Of the 88 AEs, only 28.4% (n=25) were considered at least possibly related to the intervention. Of these possibly related AEs, none were severe, 24.0% (n=6) were moderate, and the remaining 76.0% (n=19) were mild (Table 2).

With respect to the primary outcome, chi-square test showed no statistically significant association between the severity of the AEs and their relationship to the trial (p=.73). Regarding the secondary outcome, a chi-square test assessing whether AEs were unevenly distributed across treatment arms was not statistically significant (p=.48).

For both unrelated and related AEs, the most commonly reported were musculoskeletal. These included low back, hip, and knee pain. The next most common AEs were cardiovascular (hypertension) and viral illnesses (excluding COVID 19) (Figure 1). For the related AEs, 68.0% (n=17) were classified as musculoskeletal and 24.0% (n=6) were cardiovascular.

Outcome & Management of Adverse Events

The majority of participants (73.8%) who reported either a related or non-related AE required modification to the physical intervention to allow them to continue to participate. The most common modification to the physical exercise was either to change the duration or the intensity of the exercise intervention. Two participants required discontinuation of their intervention and were withdrawn from the study as a result of an unrelated AE (Figure 2).

At the end of the 16-week intervention phase of the study, 85.2% of the AEs were resolved without sequelae. For the remaining 13 AEs, nine required ongoing medical management for medication monitoring and three were recovered with minor sequelae.

DISCUSSION

SYNERGIC@Home demonstrates that adverse events, both related and unrelated, can be safely managed in a remotely delivered, asynchronous intervention trial by developing and adhering to standardized operating procedures. In this study, there were no serious intervention-related AEs, the majority of AEs were musculoskeletal in nature, and AEs were managed through modifications to the physical exercise interventions.

Older adults often cite a fear of injury or concerns about worsening of chronic conditions as barriers to participating in physical exercise interventions.[26] Therefore, being able to demonstrate that one can effectively manage AEs in a remotely delivered exercise intervention is an important finding. Only two participants had their participation discontinued due to an AE, but neither of the AEs was related to the intervention.

TABLE 1.
Demographic profile of participants

Description of Population	*Arm 1 (n=15)*	*Arm 2 (n=15)*	*Arm 3 (n=15)*	*Arm 4 (n=15)*	*Total (N=60)*
Age, mean (SD)	69.5 (6.7)	67.2 (5.8)	70.8 (5.9)	70.5 (7.4)	69.5 (6.5)
Sex, # participants (%)					
Female	9 (60.0)	9 (60)	11 (73.3)	14 (93.3)	46 (76.7)
Male	6 (40.0)	4 (26.7)	1 (6.67)	3 (20.0)	14 (23.3)
Language, # participants (%)					
English	12 (80.0)	12 (80.0)	11 (73.3)	12 (80.0)	47 (78.3)
French	3 (20.0)	3 (20.0)	4 (26.7)	3 (20.0)	13 (21.7)
Location of Residence, # participants (%)					
Rural	4 (26.7)	6 (40.0)	5 (33.3)	10 (66.7)	25 (41.7)
Suburban	8 (53.3)	6 (40.0)	2 (13.3)	3 (20.0)	19 (31.7)
Urban	3 (20%)	3 (20%)	8 (53.3)	2 (13.3)	16 (26.7)
Level of Education, # participants (%)					
High School/Community College	5 (33.33)	8 (53.3)	8 (53.3)	5 (33.3)	26 (43.3)
University Undergraduate Degree	5 (33.3)	4 (26.7)	3 (20.0)	7 (46.7)	19 (31.7)
University Graduate Degree	5 (33.3)	3 (20.0)	4 (26.7)	3 (20.0)	15 (25.0)
Level of Physical Activity, Mean (SD)					
Number of Steps/Day	4000 (3928.2)	4027.11 (2071.2)	3190.33 (2715.1)	3194.53 (2658.2)	3602.7 (2767.2)
Number of Sit-to-Stand in 60 Sec	19.93 (7.7)	19.4 (2.6)	20.2 (6.0)	20.13 (3.3)	19.9 (5.2)
Lawton-Brody Activities of Daily Living Score	22.7 (0.8)	22.9 (0.3)	22.6 (1.6)	22.9 (0.5)	22.8 (0.9)
Functional Activities Questionnaire	0 (0.0)	0.2 (0.6)	0.3 (1.3)	0.6 (1.4)	0.3 (1.0)
Dementia Risk Factors, Mean (SD)					
Number of Dementia Risk Factors	4.8 (2.0)	4.7 (1.5)	4.5 (1.4)	4.5 (1.3)	4.6(1.5)
Type of Risk Factor, # participants (%)					
Poor Sleep	12 (80.0)	11 (73.3)	12 (80.0)	10 (66.7)	45 (75.0)
Poor Diet	11 (73.3)	12 (80.0)	10 (66.7)	10 (66.7)	43 (71.7)
First Degree Relative with Dementia	11 (73.3)	11 (73.3)	8 (53.3)	11 (73.3)	41 (68.3)
Physical Inactivity	9 (60.0)	9 (60.0)	10 (66.7)	12 (80.0)	40 (66.7)
Hypertension	7 (46.7)	10 (66.7)	8 (53.3)	6 (40.0)	31 (51.7)
Dyslipidemia	7 (46.7)	7 (46.7)	9 (60.0)	7 (46.7)	30 (50)
Obesity	7 (46.7)	6 (40.0)	8 (53.3)	5 (33.3)	26 (43.3)
Diabetes	6 (40.0)	3 (20.0)	2 (13.3)	2 (13.3)	13 (21.7)
Cardiovascular Disease	2 (13.3)	1 (6.7)	1 (6.7)	4 (26.7)	8 (13.3)
Medications, Mean (SD)	3.9 (3.2)	2.8 (2.0)	4.8 (2.9)	2.7 (2.5)	3.6 (2.76)
Type of Prescription Medications, # participants (%)					
Cardiovascular (%)	6 (40.0)	10 (66.7)	10 (66.7)	4 (26.7)	30 (50.0)
Lipid Lowering (%)	6 (40.0)	5 (33.3)	9 (60.0)	5 (33.3)	25 (41.7)
Diabetic (%)	6 (40.0)	6 (40.0)	10 (66.7)	5 (33.3)	27 (45.0)

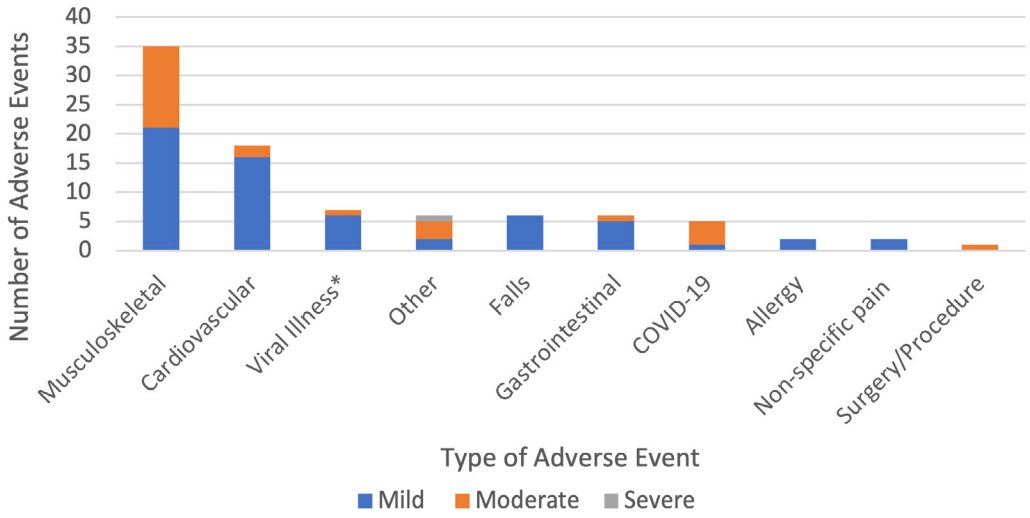
TABLE 2.
Number and severity of adverse events (AEs) related or unrelated by intervention arm (N=88)

Primary Outcome						
	AE Relation to Trial					
	Not Related	*Unlikely*	*Possibly*	*Definitely*	*Total*	*Sig*
AE Severity	47 (53.4%)	16 (18.2%)	17 (19.3%)	8 (9.1%)	N=88	χ^2 (*p*)
Mild	33	9	12	7	61 (69.3%)	3.59 (.731)
Moderate	13	7	5	1	26 (29.5%)	
Severe	1	0	0	0	1 (1.1%)	
Secondary Outcomes						
	Treatment Arm[a]					
	Arm 1	*Arm 2*	*Arm 3*	*Arm 4*	*Total*	*Sig*
All AEs	28 (31.8%)	22 (25.0%)	19 (21.6%)	19 (21.6%)	N=88	χ^2 (*p*)
Mild	18	14	15	14	61 (69.3%)	2.46 (.484)
Moderate	9	8	4	5	26 (29.5%)	
Severe	1	0	0	0	1 (1.1%)	
Related AE[b]	7 (28.0%)	5 (20.0)	7 (28.0%)	6 (24.0%)	N=25	χ^2 (*p*)
Mild	3	5	5	6	19 (76.0%)	.440 (.932)
Moderate	4	0	2	0	6 (24.0%)	
Severe	0	0	0	0	0 (0.0%)	

[a]Arm 1= Combined exercise (AE+RT) + Cognitive training (NEUROPEAK^{TM}); Arm 2= Combined exercise (AE+RT) + Control cognitive training (WS+V); Arm 3= Control exercise (BAT) + Cognitive training (NEUROPEAK^{TM}); Arm 4= Control exercise (BAT) + Control cognitive training (WS+V).
[b]Possible or definite.

Previous research by Fyfe *et al*. with community-dwelling older adults reported that 7.0% of participants had minor AEs requiring modification to the exercise intervention and 25.0% had minor musculoskeletal AEs related to the interventions that did not affect participation.[14] For SYNERGIC@Home, 48.0% of related AEs were mild, musculoskeletal, and were managed by modification to the interventions. There was no statistically significant relationship between AE severity and intervention type, which aligns with the main findings by Niemeijer *et al*.[12] who reported no increase in risk of serious AEs when participating in exercise interventions compared to the non-exercise control.

Research examining AEs in exercise interventions targeting older adults has commented on the underreporting of AEs and the importance of reporting for managing the AEs.[13] While SYNERGIC@Home did report, monitor, and manage each AE successfully, this process was time consuming, and required that research staff, including the study physician,



[a]Excluding COVID-19.

FIGURE 1. Type and severity of adverse events

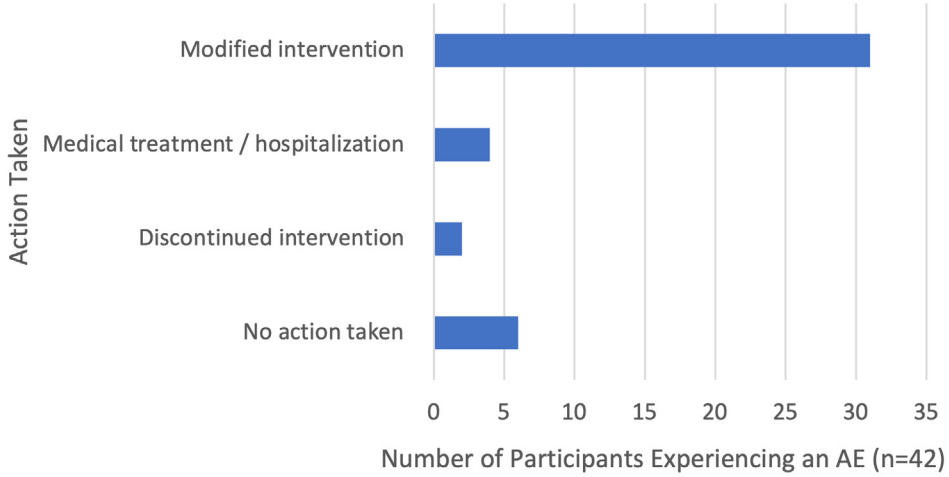


FIGURE 2. Type of action required by participants with an adverse event

were available at all times to the RAs overseeing the remote interventions. Interventions for this study had a staggered enrolment which meant that coverage had to be provided for 16 months. Ongoing AEs, such as elevated blood pressure or chronic musculoskeletal issues, were reported on weekly for the duration of the 16-week intervention, whereas newly developing AEs might be reported on for each intervention session (three times per week). The resources required to report and manage all AEs represent a significant investment in the research process and should be adequately supported.

A limitation to the study is that participants were not frail, as determined by the mean CFS score of 2.4. Therefore, these findings are not generalizable to all older adults, particularly those that have higher degrees of frailty. Moreover, due to the smaller proportion of men enrolled in this study, the findings may be biased toward overrepresenting the experience of women. Although the possibility of underreporting AEs by participants cannot be ruled out, it was likely mitigated by the standardized operating procedures in place, and the ongoing communication between participants and study staff throughout the intervention. SYNERGIC@Home's intervention phase was only 16 weeks; therefore, AEs with longer latency (e.g., overuse injury) may not have been reported during the study. A longer study with a larger sample size would be required to evaluate the risk of delayed AEs.

CONCLUSION

SYNERGIC@Home, which delivered physical exercise and cognitive training interventions remotely to community dwelling older adults at risk of ADRD, was able to capture, monitor, and manage all adverse events occurring during the intervention phase of the study. The process of reporting and monitoring the AEs allowed for modifications to the interventions to be implemented, facilitating ongoing participation. Nearly all AEs were unrelated to the interventions and mild in nature. This study demonstrated that it is possible to deliver remote dementia prevention interventions over a short term in a safe manner, and that tracking and managing adverse events, both related and unrelated, is important to ensure ongoing participation. A larger study over a longer period of time which tracks AEs would be needed to ensure that safety could be maintained over the long term for remote delivery to this population.

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CONFLICT OF INTEREST DISCLOSURES

We have read and understood the *Canadian Geriatrics Journal*'s policy on conflicts of interest disclosure and declare that we do not have any to disclose.

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Correspondence to: Pamela Jarrett, MD, FRCPC, Horizon Health Network and Dalhousie Medicine New Brunswick, Hilyard Place, Unit A200 – 560 Main St., Saint John, NB E2K 1J5
E-mail: Pam.Jarrett@HorizonNB.ca