STUDY PROTOCOL

Web-based technology and cognitive training: improving executive control in cognitively healthy older adults

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Objectives

We built on our previous brief feasibility study to design a pilot randomized controlled trial (RCT), extending the duration, and increasing the frequency and difficulty of the online Breakfast Game. The main aims of this RCT were: 1) to assess the recruitment feasibility (e.g., adherence and retention) of the online Breakfast Game delivered in a 12-session regimen, 3 times a week; 2) to evaluate the training gains of Breakfast game with Emphasis Change (EmCh) strategy (experimental group) over a similar condition with the Breakfast Game without strategy (control group), and 3) transfer effects of Breakfast game with EmCh over a similar condition with only the Breakfast game, through neuropsychological measures and psychosocial questionnaires; as well as the 4) acceptability of the program through a qualitative post-intervention questionnaire. We hypothesized robust feasibility and acceptability of the program in both groups, but greater training gains and transfer effects in the EmCh group compared to the control group.

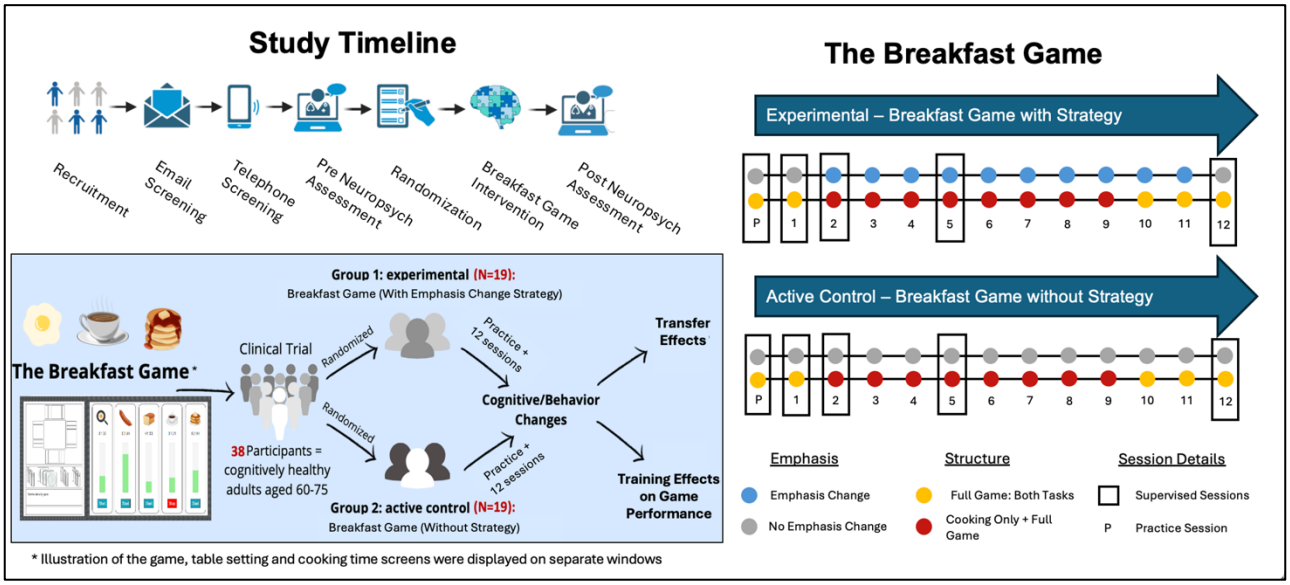
Study Design

This was a randomized, controlled, parallel-group, assessor-blinded clinical trial comparing the effects of two conditions in an online cognitive training program (experimental vs. active control) among cognitively unimpaired older adults. Following the National Institute of Health for Behavioral Intervention Development classification, this study extends our previous feasibility trial stage 1A to stage 1B, targeting the effects of an extended pilot protocol using an RCT design.

Eligible participants were randomly assigned to the two conditions with an allocation ratio of 1:1 in blocks of 20 participants. The randomization schedule was generated by the study statistician (through randomize.net) and concealed until the eligible participant was ready for enrollment. The study employed a fully remote, online design (**Figure 1**) consisting of a telephone screening, followed by informed consent, baseline assessment, one mock/practice session, 12 cognitive training sessions, and post-intervention assessment. To reduce bias, the research team conducting the online assessments was blind to the participants' group allocation, while the

researchers (including the principal investigator) supervising the online intervention sessions were blind to the participants' assessment performance. Although participants were aware of the two group interventions, they were not provided with the overall study hypotheses. Participant recruitment and interventions were conducted from February 2023 to July 2024.

Figure 1. Study Design



Ethics Approval, Registration, and Online Consent

The study protocol and documents were reviewed and approved by the Internal Review Board (IRB) of the College of Physicians and Surgeons of Columbia University (reference: IRB-AAAT4773). The study was conducted according to the Declaration of Helsinki and reported in line with the Consolidated Standards of Reporting Trials (CONSORT 2010) guidelines (Supplementary Material, Figure 1S). As the study was implemented remotely, before enrollment, the online written informed consent to participate was obtained from each participant through a secure electronic signature system after clarifications over the telephone or videoconference. The trial was registered on clinicaltrials.gov (NCT05506852; 08/18/2022). The first participant was enrolled on 28th of April 2023, and the last participant on 10th of May 2024.

Recruitment and Eligibility

Participants were recruited through multiple sources, primarily leveraging Columbia University's RecruitMe platform, a web-based system developed to connect researchers with potential research participants. Additional recruitment occurred via clinicaltrials.gov and community outreach through flyers posted in the university and communal spaces, emails to university affiliates, health providers, social media, and partnerships with organizations serving older adults in New York City (i.e., NGO's and senior centers). Interested participants contacted the research team via email and then underwent telephone screening to determine eligibility. As this was an online study, participants living in different states in the USA were allowed to participate. During the telephone screening, the study staff assessed study eligibility and clarified topics of the consent process and study procedures. If the participants were eligible, they received the consent form via email and then scheduled a follow-up call.

Eligible participants were older adults between the ages of 60 and 75 years old, of any gender/sex, or racial/ethnic background, who were native English speakers, able to read in English, and willing to adhere to the intervention protocol (which included attending 15 online visits over three months). As in our feasibility trial, we kept the age range limited to a young older adult group (60 to 75 years old) to attenuate age differences that could interfere with the current "proof-of-concept" pilot study. Participants were not required to have a computer or internet at home, as the study team would provide a laptop with internet and a mouse during the study. However, participants were required to have a minimum computer experience (including using a computer and a mouse) based on a score ≥ 10 points on the Computer Proficiency Questionnaire (CPT). Furthermore, if participants had no experience using the videoconference platform, instructions and training were provided as needed. Critically, participants had to be cognitively unimpaired, based on a score ≥ 26 points on the Montreal Cognitive Assessment-video conferencing version (MoCA-VC), and preserved functionality in the Instrumental Activities of Daily Living-Extended scale (IADL-X). Participants were excluded if they presented a history of major neurological and psychiatric conditions (e.g., stroke, traumatic brain injury, seizure disorders, bipolar disorder, schizophrenia, psychosis, substance dependence, or ADHD), or if considered to present cognitive impairment based on the comprehensive neuropsychological assessment. Individuals were also excluded if they had a recent

(i.e., past five years) history of major depressive or anxiety disorders, use of cognition-impairing medications or treatments (e.g., chemotherapy), sensory (e.g., visual, auditory) or physical impairments (e.g., severe arthritic) that interfered with computer use, or if they were enrolled in a concurrent interventional study.

Baseline Assessment

Eligible participants underwent neuropsychological assessment over videoconference, which included tests of vocabulary (American National Adult Reading Test - AMNART); episodic memory (Selective Reminding Test - SRT), and executive functions, attention and speed processing, including: Letter-Number Sequencing (Wechsler Adult Intelligence Scale - WAIS-III)[63], Stroop Color-Word Test (Delis-Kaplan Executive Function System; D-KEFS), Wisconsin Card Sorting Test (WCST - 128 cards - digital version through Milliseconds platform), and Useful Field of View (UFOV – digital version through Milliseconds platform).

Furthermore, participants were asked to perform the Alphanumeric Task (digital version through the Milliseconds platform), an experimental dual task shown to be sensitive to cognitive training. This task requires participants to perform two tasks simultaneously under different attention allocation demands: they were asked to judge the accuracy of a set of visually presented Alphanumeric Equations (by pressing F as false, or T as true). The equations were addition or subtraction constructed by combining a letter and a number (1 or 2) in the form: letter +/- number = letter (e.g., P+2 = R). At the same time, participants had to perform the Visual Detection task when they were presented with a series of white and red rectangles and were asked to detect the red one by pressing the space bar key with their left thumb. Depending on the trial, participants were asked to allocate attention equally between the tasks (i.e., 50% in each task) or prioritize one task over the other, with different emphasis in each task (e.g., 80% in one task, 20% in another task). As detailed elsewhere[54], the Alphanumeric Task was presented in five blocks, each block was composed with rest (20 second) and five tasks conditions: 1) single-task alphanumeric equation, 2) single-task visual detection, 3) dual-task with equal division of attention (50%: Equation: 50/50), dual-task with more emphasis on equation (80% Equation: 80/20) and dual-task with more emphasis on detection (20% Equation: 20/80). Each task condition lasts 40 seconds and comprises eight trials each.

Furthermore, participants were asked to complete questionnaires, including the Everyday Cognition Scale (ECOG-Revised), General Self-Efficacy questionnaire (GSE); Cognitive Leisure Activity Scale (CLAS), Beck Depression Inventory (BDI), and Beck Anxiety Inventory (BAI)[2].

Intervention

The Breakfast Game

The Breakfast Game aims to simulate a multitasking virtual environment where the player is asked to prepare breakfast, which requires setting tables for guests while concurrently cooking food for the breakfast meal. As previously described, in cognitive healthy young[52] and older adults[73], the game goals were to: (1) set as many correct tables as possible, (2) cook each food item in its accurate time (i.e., not over- or undercooking), and (3) finish cooking all food items at the same time so they could be served together. Scoring measures combined performance on the Table Setting and Cooking tasks, and the overall goal was to achieve a better performance in both tasks. Participants were asked to play the game under split-screen mode, in which they were not allowed to visualize the two tasks at the same time, simulating two different home environments. Participants were allotted a practice/mock session before starting the actual training sessions.

During the Table Setting Task, participants were instructed to set as many tables as possible (i.e., setting plates, knives, forks, and spoons) for four guests. The task followed Western etiquette (i.e., forks should be set on the left side of the plate, knives on the right side, and spoons on the right side of the knives). When setting the tables, participants were asked to follow two possible rules: by guest or by tableware. To set the table by guest rule, the participant was required to place the complete tableware set for one guest before moving to the next. To set the table by tableware rule, the participants had to set each tableware at once for all four guests before moving on to the next tableware (e.g., knives down first, then forks, etc.). Rule orders varied across trials and sessions, and one point was allocated when a full table was set under the correct rule, resulting in the task score: the *Number of Correct Tables*.

During the Cooking Task, participants were asked to prepare five food items, each of which had different

cooking times displayed in minutes (coffee: 4.5, sausage: 3.5, pancakes: 2, egg: 1.5, and toast: 1 min). The cooking times were always the same throughout the training. During each trial, visual bars displayed the cooking duration for each item. Participants initiated each trial by starting the food item with the longest cooking time (i.e., the coffee). To initiate cooking, participants were required to press the "start" button for each food and press "stop" once cooking was complete. Ideally, each food item should start "being cooked" at an accurate start time, such that cooking all items ended in synchrony and foods could "be served" together. All rounds of the game always presented five food items. EmCh instructions varied across game rounds and sessions, focused sometimes on the Table task or Cooking task (EmCh instructions detailed below). Two scores were calculated for the Cooking task: *Cooking Discrepancy* (time accuracy of cooking each food) and *Cooking Stop Time Difference* (time synchrony of finishing the foods together). Score calculations are detailed in the Outcomes section. The Breakfast Game platform was hosted by the Technion Institute of Technology (Israel), which provided technical support. The research team had access to the platform to design training features, monitor participant activity, and adherence.

Practice/mock session

Before starting the actual training program, participants were invited to attend a practice session through videoconference with research staff. Participants received instructions on how to access and play the Breakfast Game and were incentivized to ask for clarifications. They also received assistance in troubleshooting potential technical difficulties (e.g., videoconference issues or bugs in the computer), and guidance on the procedures to avoid distractions and interruptions (e.g., a silent environment and cellphones off), including the ideal moments to have short breaks (e.g., between game rounds). During the session, the participant shared the screen so the research member could observe the session. The participants played 8 short rounds of the game, with progressive difficulty. First, they practiced each task separately, and then an easier version of the "real" game: 1) two tasks simultaneously but on the same screen (not split screen mode), 2) fewer than 5 food items. In the last two trials, participants played the game under the same format as the real game (e.g., split-screen mode and 5 food items). This initial session lasted approximately 1 hour.

Session 1 to 12: Emphasis Change Strategy versus Active Control

Participants were randomly assigned to one of two groups: the experimental group, which played the Breakfast Game with Emphasis Change (EmCh) strategy, or the active control group (No-EmCh), which played the game without EmCh instructions. The control group served to account for all training procedures except EmCh exposure, allowing the evaluation of its effects on cognition. Therefore, the control group was instructed to treat all game elements as equally important, which maintained a fixed attention strategy throughout the task. In contrast, the EmCh group received instructions to direct their attention and prioritize different aspects of the game across the game rounds, thereby encouraging flexible attention allocation. Examples of EmCh instructions were similar to our previous feasibility trial[55]: 1) Emphasis on the Table Setting Task: *"Pay attention to the Table task, 75% of your scores will be based on it"*; 2)Emphasis on the Cooking Task: *"Pay attention to the Cooking task, 75% of your scores will be based on it"*; 3) Emphasis on different aspects of the cooking such as 2.1) Emphasis on Cooking Discrepancy: *"Pay attention to cooking each food in its accurate time, 75% of your scores will be based on it"*; 2.2) Emphasis on Cooking Stop Times: *"Pay attention to finishing the foods together, 75% of your scores will be based on it"*.

The structure of sessions was consistent across the 12 sessions and included: split screen mode, eight game rounds lasting 4.5 minutes each, resulting in a session of 45 minutes. Participants were instructed not to complete more than one session per day, which was also enforced by the platform, as it would not allow two sessions on the same day, and to avoid gaps of more than four days between sessions. The intervention protocol is summarized in the Supplementary Material (Figure 2S). Briefly, in session 1, participants from both groups played the game without receiving any EmCh instructions, serving as a baseline session. During sessions 2 through 11, the experimental group received EmCh instructions, which directed their attention both within the Cooking task only and across the Cooking and Table Setting tasks. In contrast, the control group continued to play the game without EmCh instructions in all sessions, following the standard gameplay format. Session 12 mirrored session 1 and functioned as a post-EmCh assessment, with both groups playing the game without EmCh instructions. Furthermore, as illustrated in Figure 1 (highlighted in red and yellow circles), during sessions 1, 10, 11 and 12,

all participants played the 8 rounds of the game in a "full game" format (Table + Cooking); while in sessions 2 to 9, the game was played in a "partial" format, with 4 rounds of the game as "cooking only" and 4 rounds as "full game". We implemented this approach to facilitate EmCh use in different game formats. To ensure clarity and support adherence to the protocol, the research team monitored participant performance through the platform system and supervised sessions 1, 2, 5, and 12 (30% of the sessions) through videoconference.

Outcomes

Recruitment, Adherence, and Retention

Recruitment was defined as the percentage of potentially eligible participants who approached the team and those who were, in fact, enrolled in the study. Recruitment characteristics were described to better map potential barriers, difficulties, and interest of participants in being part of the study. Previous remote cognitive training to older adults frequently shows high adherence and retention rates, such as 80% to > 94%; therefore, for the present study, we conceptualized intervention adherence as at least 80% of session completion (10/12 sessions within 6 weeks). Retention rate was conceptualized as the proportion of enrolled participants who completed 100% of the study, including all intervention sessions and the post-intervention assessment.

Primary Outcomes: Training Gains in the Breakfast Game and Near-Transfer

Similar to our previous studies, three game outcomes were generated after each game trial: (1) *Number of Correct Tables*, or the number of full tables completed under the correct rule (by tableware or by guest), with higher scores reflecting better performance; (2) *Cooking Time Discrepancy* (in seconds), reflecting the accuracy of cooking each food (i.e., the difference between the required and actual cooking times, averaged across all foods); and (3) *Cooking Stop Time Difference* (in seconds), reflecting the synchrony of finishing the foods together (i.e., the difference between the first and last food stopped). For both measures, lower scores indicated better performance.

The Alphanumeric Task under the 80% priority condition was one of the primary near transfer outcomes. In this condition, the participants were asked to prioritize one task over the other (e.g., Alphanumeric Equation or the Visual Detection task); therefore, this condition was the closest related to the EmCh approach, and more likely to serve as a transfer measure. The two variables under the 80% priority condition were: 1) *Alphanumeric Task 80% on Detection Task - Total Correct*, and 2) *Alphanumeric Task 80% on Equation Task – Total Correct*. Furthermore, based on a previous model of executive control, we created an Executive Control Composite Score based on measures of working memory (Letter-Number Sequencing total score), cognitive flexibility (WSCT – perseverative responses), inhibitory control (Stroop Color-Word Test-DKEFS Condition 3 – Inhibition, and Condition 4 - Inhibition and Switching), and divided attention (UFOV – Divided Attention Accuracy)[66]. The composite score was created by summing the z-scores of each of the five tests.

Secondary Outcomes: Distant Transfer Outcome

Additional measures were used to assess potential psychosocial changes after the intervention, including the measure of self-efficacy (GSE), engagement in cognitive activities (CLAS), and mood questionnaires targeting symptoms of depression (BDI) and anxiety (BAI).

Acceptability: Post-Intervention Questionnaire

Acceptability was assessed based on participants' quantitative and qualitative responses in the post-intervention questionnaire[5]. Participants were asked to provide scores (0 to 10) and their views on specific aspects of the cognitive training program. For instance, they were asked to provide scores on the difficulty and enjoyability of the game, clarity of instructions, and accessibility of the platform. They were also asked to rate their overall experience in the study. Moreover, participants were asked to answer open-ended questions about the game and its influence on their daily lives.

Statistical Analysis

For the sample size calculation, we considered our previous preliminary data and the flat rule of thumb of at least 30 subjects to estimate a parameter. Therefore, the current sample size (N=38) would overcome the sample size from previous similar studies, including 10 young adults, and 15 to 18 older adults per group. The power analysis was conducted with the assumption of 5% attrition between evaluations, having 80% power at α=0.05.

At baseline, the overall sample was described, and comparisons between groups were assessed. The Independent samples T-test was applied for the continuous variables, and chi-squared tests were used for the categorical variables. All outcomes were analyzed following the intent-to-treat principle. To evaluate intervention effects, linear mixed models (LMM) were conducted using the lme4 R package (version 4.5.0). Each model included fixed effects for time (pre vs. post; or session 1 vs. session 12 on the Breakfast Game outcomes), group (experimental vs. control), and the interaction between time and group, with a random intercept for each participant to account for within-subject correlation. Baseline cognitive performance was included as a covariate in all LMM to control for individual variability at baseline. The primary analysis tested time-by-group interactions in the training gains and near-transfer measures, and the secondary analysis examined interactions in the distant transfer measures. Of note, all the Breakfast Game outcomes were based on the trial performance across sessions.

Multiple-comparison corrections across all six outcomes were performed to control the false discovery rate (FDR) using the Benjamini-Hochberg (BH) procedure. Adjusted p-values (q-values) less than 0.05 were considered significant. In addition, effect sizes (Cohen's d) were calculated for the outcome that presented a significant time-by-intervention group interaction. All analyses and visualizations were performed using the R Studio software (version 4.3.1).

Supplementary Material

Figure 1S. CONSORT Check List

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	3-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5-6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	6-7
	4b	Settings and locations where the data were collected	6-7
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	8; 11-13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	6
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	6
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	6
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	6

		assessing outcomes) and how	6
	11b	If relevant, description of the similarity of interventions	10-11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	13-14
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13-14
Results			18
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	14-15; Figure 2
	13b	For each group, losses and exclusions after randomisation, together with reasons	14-15; Figure 2
Recruitment	14a	Dates defining the periods of recruitment and follow-up	6
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	15; Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	14-15; Figure 2
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16-19; Tables 2 & 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	18
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	21
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19-20
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-21
Other information			
Registration	23	Registration number and name of trial registry	6
Protocol	24	Where the full trial protocol can be accessed, if available	6; Supplementary Material
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	22

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Figure 2S. Intervention Protocol Details

Session Number	Intervention Phase	Level of Supervision	Trials Structure	Duration	Session Structure	Tasks Presentation	Cooking Task	Table Setting Task Rules	EmCh Instructions (Experimental Group only)
1	**Mock Session:** Instruction and practice	Supervised	Instructions + practice 8 trials of 4.5 min each	1h20 min	Full Game: Both Tasks	Same screen/ Split screen	2-5 foods: Gradual Progression	By Tableware or Guest (random)	**No**
2	**Intervention Session 1:** (Baseline Pre EmCh)	Supervised	8 trials of 4.5 min each	45 min	Full Game: Both Tasks	Split screen	5 foods	By Tableware or Guest (random)	**No**
3	**Intervention Session 2:** EmCh or Regular Game	Supervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Guest	**Yes** Within cooking + across both tasks
4	**Intervention Session 3:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Tableware	**Yes** Within cooking + across both tasks
5	**Intervention Session 4:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Guest	**Yes** Within cooking + across both tasks
6	**Intervention Session 5:** EmCh or Regular Game	Supervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Tableware	**Yes** Within cooking + across both tasks
7	**Intervention Session 6:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Tableware	**Yes** Within cooking + across both tasks
8	**Intervention Session 7:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Guest	**Yes** Within cooking + across both tasks
9	**Intervention Session 8:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Guest	**Yes** Within cooking + across both tasks
10	**Intervention Session 9:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Cooking only + Full game (both tasks)	Split screen	5 foods	By Tableware	**Yes** Within cooking + across both tasks
11	**Intervention Session 10:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Full Game: Both Tasks	Split screen	5 foods	By Tableware or Guest (random)	**Yes** Within cooking + across both tasks
12	**Intervention Session 11:** EmCh or Regular Game	Unsupervised	8 trials of 4.5 min each	45 min	Full Game: Both Tasks	Split screen	5 foods	By Tableware or Guest (random)	**Yes** Within cooking + across both tasks
13	**Intervention Session 12:** (Post EmCh)	Supervised	8 trials of 4.5 min each	45 min	Full Game: Both Tasks	Split screen	5 foods	By Tableware or Guest (random)	**No**