Grant Title: The emergence of abstract structure knowledge across learning and sleep

NCT number: NCT05746299

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		Aim 1	Aim 2
4.1 Brief Summary			
4.1	**Brief Summary**	The objective of this study is to determine whether learning a category with a certain structure in Stage 1 improves learning of a new category with the same structure in Stage 2. The primary endpoint is accuracy on the missing feature task in Stage 2.	The objective of this study is to evaluate the contribution of sleep to the consolidation of abstract structural representations. The primary endpoint is accuracy in the missing feature task in Stage 2, administered after the delay period.
4.2 Study Design			
4.2.a	**Narrative Study Description**	Participants will be randomly assigned to a Congruent or Incongruent Structure Group. The intervention consists of a missing feature task in Stage 1 in which each participant learns a novel category whose structure is determined by their assigned group. In Stage 2, we will use another missing feature task to expose participants to a new category whose structure is identical to the category learned by the Congruent group in Stage 1. We will assess the effect of our intervention by comparing accuracy on the missing feature task across groups in Stage 2. Our planned sample size of N =100 results in statistical analyses with N =50 which is sufficient to detect our expected effects.	Aim 2 includes Stage 1, a delay, and Stage 2. Participants are assigned to different experimental conditions such that some particpants learn only Lattice categories in Stage 1 (Incongruent) while others are exposed to a Modular category (Congruent). Participants are also assigned to Awake or Sleep groups. Categories in Stage 1 are paired with different auditory tones to be used later in TMR in the sleep groups. All participants learn a new Modular category in Stage 2. The Awake participants (Incongruent and Congruent) remain awake during the 2 hour delay between Stage 1 and 2. Sleep participants are given a nap opportunity during the delay while sleep stages are monitored with EEG. For particpants who learned a Modular as well as a Lattice category in Phase 1, TMR will be used to selectively activate the Lattice (Incongruent) or Modular (Congruent) category. Participants in the Sleep Control group learned two Lattice categories in Phase 1 one of which will be reactivated with TMR. We will assess the effect of our intervention by comparing missing feature task accuracy in Stage 2 across groups. Accounting for an expected 20% attrition rate in the sleep groups, we plan to collect data from 173 participants, resulting in a final planned sample size of N =150. This results in statistical analyses with N =30 which is sufficient to detect our expected effects, based on previous studies using these methods.
4.2.b	**Primary Purpose**	Basic Science	Basic Science
4.2.c	**Interventions**		
	Intervention Type	Behavioral	Behavioral
	Name	Learning either a Modular or Lattice category in Phase 1	Awake vs. Sleep, Lattice vs. Modular category in Phase 1, and TMR for either abstract Modular or Lattice structure during the sleep period
	Description	Participants will either learn a Modular or a Lattice category in Phase 1. Then all particpants will learn a new Modular category in Phase 2. Ability to learn the new Modular category will be assessed to determine effect of intervention.	The Awake vs. Sleep intervention determines whether participants remain awake or take a nap during the delay period. The Lattice vs. Modular intervention determines whether participants learn two Lattice categories in Phase 1, or one Lattice and one Modular category. The TMR intervention determines whether TMR is used to reactive a Lattice or Modular category during the nap session. After the delay, ability to learn a new Modular category in Phase 2 will be assessed to determine effect of interventions.
4.2.d	**Study Phase**	Other	Other
4.2.e	**Intervention Model**	Parallel: Participants will either learn a Modular or a Lattice concept in Phase 1.	Parallel: Participants will be assigned to either an Awake-Congruent, Awake-Incongruent, Sleep-Congruent, Sleep-Incongruent, or Sleep-Control group.
	Number of Arms	2	5
4.2.f	**Masking**	Participant, investigator	Participant
4.2.g	**Allocation**	Randomized	Randomized
	Enrollment	100	173
4.3 Outcome Measures			
4.3	**Name**	Structure knowledge for a new Modular category in Stage 2.	Structure knowledge for a new Modular category in Stage 2.
	Type	Accuracy	Accuracy
	Time Frame	Final accuracy is collected in a missing feature task which occurs 25 minutes after the experiment begins and takes 25 minutes to complete. Stage 1 and Stage 2 will take 50 minutes to complete.	Final accuracy is collected in a missing feature task which occurs 2 hours and 50 minutes after the experiment begins and takes 25 minutes to complete. Stage 1, Stage 2, and the intervening delay period will take 3 hours and 15 minutes to complete.
	Brief Description	The outcome measure is accuracy (0-100%) on the missing feature task in Stage 2.	The outcome measure is accuracy (0-100%) on the missing feature task in Stage 2.
4.4 Statistical Design and Power			
	# of subjects	100	150
	Expected effect size	0.85	0.85
	Power	0.98	0.85
	Statistial methods	T-test comparing accuracy between groups (N =50 each group)	T-test comparing accuracy between groups (N =30 each group)
4.5 Subject Participation Duration			
	Time to complete study	1 hour	3.5 hours
4.6 FDA-regulated invervention?			
	Yes/No	No	No
4.7 Dissemination Plan			