AUM Research Protocol Review Form

Institutional Review Board for Research Involving Human Subjects

Office of Sponsored Programs (OSP), 114 Administration Bldg 334.244-3250

Date received in OSP: PRO	Date of IRB approval:			
Type of review: Expedited, Full Board, Exempt	Interval for Continuing Review:			
Proposed dates of study: from April 21, 2014 to August 30 project Title: Increasing Functional and Core Content Sight Wintellectual Disabilities. Principal Investigator: Intellectual Disabilities. Principal Investigator: Intellectual Disabilities. Principal Investigator: Intellectual Dept: ESPE Principal Investigator: Internal Intellectual Dept: Especial	Phone: 334			
Other (explain Q.12a) C. Research Content Area	D. Risks to Participants			
Identify (list) 3 or 4 keywords to identify this research project. discrete trial training sight words intellectual disabilities	Please identify all risks that may reasonably be expected a result of participating in this research: Breach of Confidentiality Deception Psychological Physical			

	Other (explain)
pective data collection involves new or original dat	a. *Retrospective data involves the use of existing data.)
INVESTIGATORS:	
	uct of this project and describe his or her roles and responsi
related to this project.	uct of this project and describe his of her roles and responsi
Principal Investigator (PI): the PI must have com-	pleted IRB-approved human research protections training
through CITI. IRB staff must verify training before through the following link <u>www.citiprogram.org</u>	approval is granted. The CITI training site is available
CITI completion report attached	
Name:	Email: dividual land
Department: ESPE	Phone:
Faculty Staff Graduate Student	Undergraduate Student
synthesize, dissemination.	ata, select and obtain materials for study, analyse and
Investigator: must have completed IRR-approve	d human research protections training through CITI. IRB staff
	he CITI training site is available through the following link
www.citiprogram.org	the CITI training site is available through the following link
CITI completion report attached	
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Department: ESPE	Phone:
Faculty Staff Graduate Student	Undergraduate Student
Faculty Staff Graduate Student	
Faculty Staff Graduate Student Role/Responsibility: supervise the completion of	Undergraduate Student f the project, assist with data analysis and dissemination
Faculty Staff Graduate Student Role/Responsibility: supervise the completion of Researcher: must have completed IRB-approved	Undergraduate Student f the project, assist with data analysis and dissemination human research protections training through CITI. IRB staff
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- 9. LOCATION OF RESEARCH: List all locations where data collection will take place and analyzed. Be as specific as possible. Sessions will be conducted in the participant's school, Peter Crump Elementary, in a self-contained classroom. Data will be stored and analyzed in the primary investigator's office. A self-contained classroom is a classroom with students with an IQ of 55 or lower. These students have moderate to severe intellectual and/or physical disabilities. The students receive the majority of their instruction based on Alabama extended standards or a modified curriculum of extended standards inside this classroom.
- 10. BACKGROUND: Briefly discuss the relevant literature and research findings that lead to the development of this project. Please cite relevant sources and include a "Reference List" as Appendix A. Research on the acquisition of functional skills by students with intellectual disabilities has been the focus for over thirty years (Brown et al., 1979). Recent legislation of No Child Left Behind Act of 2001 changed the focus of assessments to core content standards for all students including those with disabilities (Browder et al., 2003). Special education teachers have to meet federal regulations of core content and the individualized need of functional sight words. Professional literature has shown effective means of discrete and chained tasked to students with moderate to severe disabilities in both a small group and one-on-one setting (McDonell et al., 2006). A meta-analysis indicated that the interventions (massed and distributed trials) to teach sight words were highly effective when working with students that have moderate to severe disabilities (Browder & Xin, 1998). In Collins' study of acquisition and maintenance of teaching functional and core content sight words in special and general education settings, the main focus of the study included three variables: mass trial in a resource room, distributed trial in a general education classroom, and an embedded trial in a general education classroom. Collins' study focused on individualized learning. Every student learned six words that were based on their individual learning needs. These words included three functional words and three core content words, All of Collins' probed trials were conducted in the resource room or in a general education classroom. She used flashcards as the materials for mass trials and distributed trials and used worksheets for embedded trials. The experimental design was an adapted alternating treatment design across three instructional conditions and four participants. It compared two or more independent variables and two dependent variables. Visual analysis of the data was graphed to indicate the effectiveness of the treatment. The results of Collins' investigation were that each student reached criterion on sight words, functional and core content words. Some students reached mastery earlier than others, but they demonstrated both types of 100% maintenance of the core and functional content. In my replication study, I will focus on the acquisition and maintenance of functional and core content sight words in an elementary selfcontained special education classroom. The main focus of the study will include only two variables: massed trial and distributed trial; both will be completed in the special education room. Every student will be exposed to six words; three functional and three core content words. The functional words will focus on cooking terms. The core content words will still take into account the students individual needs based on the extended standards. The materials will be flashcards for both trials. Similar to the Collins (2008) research design, the experimental design will be an adapted alternating treatment design across two instructional conditions and five participants. It will compare two independent variables and two dependent variable. Visual analysis of the data will be graphed to indicate if the treatment was effective.

11. PURPOSE & SIGNIFICANCE:

- a. Clearly state the objectives, goals, or aims of this project. Research Question- Are distributed trials or massed discrete trial trainings more effective at teaching functional and core sight words to elementary students with moderate to severe intellectual disabilities? The goal of this project is to validate the Collins study. It indicates that both massed and distributed trials are equally effective when teaching functional and core content sight words. We will take that idea and apply it to a moderate to severe special education classroom and see if we get the same results. The dependent variables will include: acquisition of (1) functional sight words and (2) core sight words. The independent variables will include (1) massed trials and (2) distributed trials. Both independent variables will be conducted in the special education classroom for students with moderate to severe disabilities.
- b. How will the results of this project be used? (e.g., presentation? Publication? Thesis? Dissertation?) The results will be dissimenated through professional presentations and publications (e.g., Council for Exceptional Children Conference, Teaching Exceptional Children Journal.)

12. PARTICIPANTS:

a. Describe the participant population you have chosen for this project. Five Peter Crump Elementary School students from third, fourth and fifth grades in the self-contained special education classroom will participate individually in four thirty-minute sessions for 12 sessions. The participants will all have significant intellectual disabilities (55 or lower). Qualification will be assessed by the teacher and pretest scores. Parental consent and child assent will be obtained for participation in the study.

What is the minimum number of participants you need to validate the study? 3 What is the maximum number of participants you will include in the study? 5

- b. Describe the criteria established for participant selection. (If the participants can be classified as a "vulnerable" population, please describe additional safeguards that you will use to assure the ethical treatment of these individuals.) Data from the preassessments will be used to determine the extent to which students are struggling with mastery of Dolch sight words. A student will be selected to participate in the study if he or she scored in the frustration level (i.e., less than 50% accuracy with word recognition) on Pre-Primer and Primer Dolch sight words. Students who read both sets of words with more than 50% accuracy on the Pre-Primer and Primer Dolch words will be dismissed from the study and instead participate in their regular typical classroom activities.
- c. Describe all procedures you will use to recruit participants. Please include a copy of all flyers, advertisements, and scripts and label as <u>Appendix B</u>. Letters explaining the purpose, requirements for desired participants, benefits of the study, along with consent, will be sent home to the parents in a daily communication folder. Consent forms will be received by each participant and their legal guardians. Written consent from both the student and guardian will happen before the pre-test is completed. A

simple oral description of the child's involvement is given to the participant and verbal assent is requested. The procedure may be documented on the informed consent form by the presence of the signature of a witness. (Letter describing study's process and also gaining consent is included at the end)

- d. Describe how you will determine group assignments (e.g., random assignment, independent characteristics, etc.) Participants will be randomly assigned an order in which the discrete trial training is used. The students will be assessed individually. This study uses a single case design (repeated measures). All participants are exposed to the independent variables.
- e. Describe the type and amount and method of compensation for participants. N/A

13. PROJECT DESIGN AND METHODS:

Describe the procedures you will plan to use in order to address the aims of this study. (NOTE: use language that would be understandable to a layperson. Without a complete description of all procedures, the AUM IRB will not be able to review the protocol.

- a. Project overview (Briefly describe the scientific design.) A single subject (repeated measures) design will be employed to investigate the effects of dicrete trial training on sight words. The experiemental design employed during this investegation will adapt alternating treatments design replicated across two instructional conditions (massed and distrubuted trials) and participants (Cooper, Heron, & Heward 2007). The alternating treatment design allows for comparison of "two or more independent variables that are within that same response class but are functionally independent" (Collins, 2008).
- b. Describe all procedures and methods used to address the purpose. The conditions, functional and core sight words, will be randomly assigned for each session with no more than two consecutive sessions having the same condition. Each session, the participants will read as many words in a period of time after reviewing them using the discrete trial training. Discrete Trial Training (DTT) is a method of teaching in simplified and structured steps. Instead of teaching an entire skill all at once, the skill is broken down and "built-up" using discrete trials that teach each step one at a time. Participants will be given positive reinforcers upon conclusion of the activity. The sessions will be conducted on four consecutive days for three weeks for a total of 12 sessions. The sessions will last no longer than 30 minutes. Participants names will remain anonymous during dissemination activities. Also, each session will be audio recorded to review data collected at a later date
- c. List all instruments used in data collection. (e.g., surveys, questionnaires, educational tests, data collection sheets, outline of interviews, scripts, audio and/or video methods, etc.) Please include a copy of all data collection instruments that will be used in this project and label as Appendix C. Functional and core content sight words; data recording forms for oral reading accuracy in context and isolation, fluency; audio recording.

d. Data Analysis: Explain how the data will be analyzed. The number of new sight words learned and maintained during massed trials will be compared to the number of sight words learned and maintained during distributed trials. The rate of sight words read correctly and incorrectly will be graphed. Visual analysis of graphed data will allow the investigators to determine if each treatment is effective and accuracte by evaluating the level, trend, stability, and overlap in each condition (Cooper, Heron, & Heward 2007). Descriptive statistics (i.e., mean, median, range, and mode) will be reported for each individual participant.

14. RISKS AND DISCOMFORTS:

List and describe all of the reasonable risks that participants might encounter if they decide to participate in this research. If you are using deception in this study, please justify the use of deception and be sure to attach a copy of the debriefing form you plan to use and label as *Appendix D*. The researcher does not anticipate any risks associated with the proposed research. The risks of participating in the study are no greater than typical classroom procedure. However, there may be social, breach of confidentiality, and concern risks involved with participating in the study. Many procedures are in place to protect the confidentiality of the participants, but it is possible that students' identities may be paired with their sight word performances and demographics data (i.e., sight word fluency, DIBELS, attendance records, special education records) if there is a breach of confidentiality. Despite assuring parents and students in writing that participation will not impact their relationship with the teacher, school, or AUM, students and parents may feel coerced into participation to avoid negative ramifications for not participating.

15. PRECAUTIONS:

Describe all precautions you have taken to eliminate or reduce risks that were listed in #14. Several precautions will be taken to reduce the likelihood of risks associated with participating in the study. Identifying information will not be used in publications or presentations. Data will be maintained in a secure location and shredded upon completion of dissemination activities.. First parental consent and child assent will be obtained to reduce the risks associated with participating in the study. First parental consent and child assent forms will be used to document voluntary participation and knowledge of the procedures and risks involved. Parents and children are assured in writing that participation in the study is voluntary.

16. BENEFITS:

- a. List all realistic benefits participants can expect by participating in this study. The participants will receive extra sight word practice and individual feedback and attention that may improve their reading fluency and reading skills.
- b. List all realistic benefits for the general population that may be generated from this study. Effective methods of teaching sight words used in this study may have implications for teaching sight words to other populations and in different settings. Also, because participating students all have a low IQ, the mastery of functional and core content words could allow for greater student success and independence in the future.

17. PROTECTION OF DATA:

a. Will data be collected as anonymous? Yes No

AUM IRB Protocol Form 3.11

D.	Will data be collected as confidential? Yes No
c.	If data is collected as confidential, how will the participants' data be coded or linked to identifying information? Subject confidentiality will be maintain by assigning each participant a number. This number will be used to refer to a subject on all data collection forms and audio recording labels. During recording only first names will be used when addressing a subject.
d.	Justify your need to code participants' data with identifying information. As I am the teacher/casemanager, there is no reason to code participant data.
e.	Where will code lists be stored? The list of corresponding numbers and subjects' names will only be available to the researchers and kept in a locked file cabinet.
f.	Will data collected as "confidential" be recorded and analyzed as "anonymous"? ⊠ Yes ☐ No
g.	Describe how the data will be stored (e.g. hard copy, audio recording, electronic data, etc), where the data will be stored, and how the location where data is stored will be secured in you absence. Data, including forms and audio recording files and devices, will be kept in a locked file cabinet in the Principa Investigator's classroom.
h.	Who will have access to participants' data? The Principal and Faculty Investigator will have access to the data throughout the project.
i.	When is the latest date that the data will be retained? Recordings and data will be kept for 6 months.
j.	How will the data be destroyed? Upon completion of dissemenation, data will be shredded and erased.

PROTOCOL REVIEW CHECKLIST All protocols must include at least items 1 &2. Items 3-10 as applicable.

1.	Completed Protocol Form
2.	☑ IRB Assurances Form with signatures
3.	
4.	Appendix A "Reference List"
5.	Appendix B if flyers, advertisements, generalized announcements or scripts are used for data collection.
6.	Appendix C if data collection sheets, surveys, tests, or other recording instruments will be used for data collection. Be sure to mark each of the data collection instruments as they are identified in section #13 , part c.
7.	✓ Verification of CITI Training (completion reports) for all researchers.
8.	Appendix D if debriefing form is used.
9.	☑ If research is being conducted at sites other than AUM or in cooperation with other entities, a letter from the site/program director must be included indicating their cooperation or involvement in the project. NOTE: if the proposed research is a multi-site project, involving investigators or participants at other academic institutions, hospitals or private research organizations, a letter of IRB approval from each entity is required prior to initiating the project.
10.	Written evidence of acceptance by the host country if research is conducted outside of the United States (approval by host country IRB).

Principal Investigator's Assurance

- 1. I certify that all information provided in this application is complete and correct.
- 2. I understand that, as Principal Investigator, I have ultimate responsibility for the conduct of this study, the ethical performance for this project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the AUM IRB. I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities and are in compliance with AUM IRB policies regarding the collection and analysis of the research data. I have completed CITI training.
- I certify that all individuals involved with the conduct of this project are qualified to carry out their specified roles and responsibilities & are in compliance with AUM IRB policies regarding the collection & analysis of the research data.
- I agree to comply with all AUM IRB policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection of human subjects, including, but not limited to the following:
- a. Conducting the project by qualified personnel according to the approved protocol
- Implementing no changes in the approved protocol or consent form without prior approval from the Office of Sponsored Programs (OSP) (except in an emergency, if necessary to safeguard the well-being of human subjects)
- Obtaining the legally effective informed consent from each participant or his or her legally responsible representative prior to their participation in this project using only the currently approved, stamped consent form.
- Promptly reporting significant adverse events and/or effects to the OSP in writing within 5 working days of the
 occurrence.
- If I will be unavailable to direct this research personally, I will arrange for a co-investigator to assume direct responsibility in my absence. This person has been named as co-investigator in this application, or I will advise OSP, by letter, in advance of such arrangements.
- 6. I agree to conduct this study only during the period approved by the AUM IRB.
- I will prepare and submit a renewal request and supply all supporting documents to OSP before the approval period has expired if it is necessary to continue the research project beyond the time period approved by the AUM IRB.

8.	I will prepare and submit a final report upon com	pletion of this research project.	4/1/14	
	Principal Investigator (Please type or print)	Principal Investigator Signature	Date	

Faculty Sponsor's Assurance

- By my signature as sponsor on this research application, I certify that the student or guest investigator is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct this particular study in accord with the approved protocol. This requirement includes CITI training.
- I certify that the project will be performed by qualified personnel according to the approved protocol using conventional or experimental methodology.
- 3. I agree to meet with the investigator on a regular basis to monitor study progress.
- Should problems arise during the course of the study, I agree to be available, personally, to supervise the investigator in solving them.
- I assure that the investigator will promptly report significant adverse events and/or effects to the OSP in writing
 within 5 working days of the occurrence. If I will be unavailable, I will arrange for an alternate faculty sponsor to
 assume responsibility during my absence, and I will advise the OSP by letter of such arrangements.

6.	I have read the protocol submitted for this proj	ect for content_clarity, and methodology	4-1-14
	Faculty Sponsor (Please type or print)	Faculty Sponsor Signature	Date

Department Head's Assurance

By my signature as department head, I certify that every member of my department involved with the conduct of this research project will abide by all AUM policies and procedures, as well as with all applicable federal, state, and local laws regarding the protection and ethical treatment of human participants.

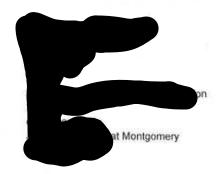
Department Head (Please type or print)	Department Head Signature	Date
Department Head (Flease type of print)	Department Head Signature	Date

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

SOCIAL & BEHAVIORAL RESEARCH - BASIC/REFRESHER CURRICULUM COMPLETION REPORT
Printed on 04/02/2014

LEARNER

DEPARTMENT
PHONE
EMAIL
INSTITUTION
EXPIRATION DATE



SOCIAL & BEHAVIORAL RESEARCH - BASIC/REFRESHER: Choose this group to satisfy CITI training requirements for Investigators and staff involved primarily in Social/Behavioral Research with human subjects.

COURSE/STAGE:

PASSED ON:

REFERENCE ID:

Basic Course/1 04/30/2013

REQUIRED MODULES	DATE COMPLETED	SCORE
Introduction	01/09/13	No Quiz
Belmont Report and CITI Course Introduction	03/03/13	3/3 (100%)
Students in Research	03/03/13	10/10 (100%)
History and Ethical Principles - SBE	04/30/13	5/5 (100%)
Defining Research with Human Subjects - SBE	04/30/13	4/5 (80%)
The Regulations - SBE	04/30/13	4/5 (80%)
Assessing Risk - SBE	04/30/13	5/5 (100%)
Informed Consent - SBE	04/30/13	5/5 (100%)
Privacy and Confidentiality - SBE	04/30/13	5/5 (100%)
Research with Prisoners - SBE	04/30/13	4/4 (100%)
Research with Children - SBE	04/30/13	4/4 (100%)
Research in Public Elementary and Secondary Schools - SBE	04/30/13	4/4 (100%)
International Research - SBE	04/30/13	3/3 (100%)
Internet Research - SBE	04/30/13	5/5 (100%)
Research and HIPAA Privacy Protections	04/30/13	2/5 (40%)
Vulnerable Subjects - Research Involving Workers/Employees	04/30/13	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects	04/30/13	2/5 (40%)
I Have Agreed to be an IRB Community Member. Now What?	03/03/13	5/5 (100%)
Auburn University at Montgomery	01/09/13	No Quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.

Paul Braunschweiger Ph.D. Professor, University of Miami Director Office of Research Education CITI Program Course Coordinator

Parental Permission for Children Participation in Research

Title: Increasing Functional and Core Content Sight Word Fluency Using DTT With Students With Intellectual Disabilities.

Introduction

The purpose of this form is to provide you (as the parent) of a prospective research study participant) information that may affect your decision as to whether or not to let your child participate in this research study. The person performing the research will describe the study to you and answer all your questions. Read the information below and ask any questions you might have before deciding whether or not to give your permission for your child to take part. If you decide to let your child be involved in this study, this form will be used to record your permission.

Purpose and Procedures of the Study

Students who have difficulties with sight words in Mrs. third-fifth grade self-contained classroom have been chosen to be the focus due to their IQ and exceptionality. If you agree, your child will be asked to participate in a research study about increasing sight word fluency using discrete trial training. The purpose of this study is to determine if the various trials (massed and distributed) will increase the fluency of functional and core content sight words.

Discrete Trial Training (DTT) is a method of teaching in simplified and structured steps. Instead of teaching an entire skill in one go, the skill is broken down and "built-up" using discrete trials that teach each step one at a time. This method is used on a daily basis in the fluency station using different flashcards.

What is my child going to be asked to do?

If you allow your child to participate in this study, they will be asked to

- Take a baseline pre-test using functional and core content sight words.
- Participate in twelve 30-minute sessions in Mrs.
 ' room focusing on increasing their fluency and knowledge using discrete trial training while being audio recorded. These sessions will happen for four days a week for three weeks.
- Take a post-test of both functional and core content sight words to show their growth. This study will take one month and there will be five students in this study. Your child will be audio recorded.

What are the risks involved in this study?

There are no foreseeable risks to participating in this study.

What are the possible benefits of this study?

The possible benefits of participation are in increase of fluency in Dolch sight words.

Does my child have to participate?

No, your child's participation in this study is voluntary. Your child may decline to participate or to withdraw from participation at any time. Withdrawal or refusing to participate will not affect their relationship with Peter Crump or Auburn University at Montgomery in anyway. You can agree to allow your child to be in the study now and change your mind later without any penalty. This research study will take place during regular classroom activities; however, if you do not want your child to participate, an alternate activity will be available.

What if my child does not want to participate?

In addition to your permission, your child must agree to participate in the study. If you child does not want to participate they will not be included in the study and there will be no penalty. If your child initially agrees to be in the study they can change their mind later without any penalty.

Will there be any compensation?

Neither you nor your child will receive any type of payment participating in this study.

How will your child's privacy and confidentiality be protected if s/he participates in this research study?

A locked file cabinet will store the data when not in use will protect your child's privacy and the confidentiality of his/her data.

Information that can be linked to your child will be protected to the extent permitted by law. Your child's research records will not be released without your consent unless required by law or a court order. The data resulting from your child's participation may be made available to other researchers in the future for research purposes not detailed within this consent form. In these cases, the data will contain no identifying information that could associate it with your child, or with your child's participation in any study.

If you choose to participate in this study, your child will be recorded. Any audio recordings will be stored securely and only the research team will have access to the recordings. Recordings will be kept for up to six months and then erased.

Whom to contact with questions about the study?

Prior, during or after your participation you can contact the researcher at (334) or send an email to edu for any questions or if you feel that you have been harmed. Questions about your child's rights as a participant can be

directed to Debra Tomblin (Research Compliance Officer) at AUM (334) 244-3250 or dtomblin@aum.edu.

Signature		
You are making a decision about allow signature below indicates that you have decided to allow them to participate it withdraw your permission for your chor her participation at any time. You	we read the information provide the study. If you later decide ald to participate in the study	led above and have that you wish to you may discontinue his
I grant permission for my cl	hild to participate in this pro	oject and be audio
recorded.		
I do not grant permission for recorded.	my child to participate in the	his project and be audio
Printed Name of Child		
Signature of Parent(s) or Legal Guardian		Date
Signature of Investigator		Date

Peter Crump Elementary School 3510 Woodley Road Montgomery, AL 36116

Auburn Montgomery
Institutional Review Board
Montgomery, AL

April 1, 2014

To whomever it may concern,

This letter is to show my support for to complete her Functional and Core Content Sight Word Fluency Discrete Trial Training here at Peter Crump Elementary School.

If you have any questions, please feel free to contact me at (334)

Sincerely,

William Shaw, Principal

Tillian R. Shan)

Correct and Incorrect Frequency Data Sheet

Ŧ	Tunction	nal				C	ore Cont	ten+		
Date & Time	Condition	Missed word (s)	+	-		Date & Time	Condition	Missed word (s)	+	
										T
					Ī					
9										-
							1			T
						2				İ
										l
										t
					-					-
										-
					-					1

Pretest Test (pre-primer and primer Dolch Sight words)

Name:			Date:
Words	+	-	
Yellow			
Where			
Play			
Jump			
Little			
Funny			
Please			
Under			
Must			
Good			
Black			3
Went			

Post Test (pre-primer and primer Dolch Sight words)

Name:			Date:
Words	+	-	
Yellow			
Where			
Play			
Jump			
Little			
Funny			
Please	-		
Under			
Must			
Good			
Black			
Went			

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