Mind, Brain, Body

Emily Towner

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Contents

Chapter 1

Introduction

The Mind, Brain, Body study looks at how early caregiving experiences influence the emotional, cognitive, and brain development, as well as physical health and wellness.

The study also explores how the bacteria that live inside us (the microbiome) are connected to the development of our brains and bodies.

Chapter 2

Checklists

2.1   Initial Checklist

Scheduling and Confirmation

- Schedule lab session
- Send confirmation email (in templates)
    - Attach Next Steps

Enrollment

- Create participant Dropbox folder using MBB_template (delete blank README from newly created folder)
- Enroll participant in Wave 1 on REDCap
- Fill participant instrument on REDCap
- Fill counterbalance order on REDCap (Checklist - Lab Session Child Instrument)
- Print MBB Lab-Session Checklist-Child
- Print MBB Lab-Session Checklist-Parent

Calendar

- Create MBB calendar event lab session and invite researchers
- Create DBS calendar event (SAND calendar)
- Create MBB calendar event lab session reminder 1 (email) (1 week prior)
- Create MBB calendar event lab session reminder 2 (email and call) (3 days prior)
- Create MBB calendar event to send home session reminder 1 (email) (1 week after lab session)

- Create MBB calendar event to make home session reminder 1 (call) (8 days after lab session)
- Create MBB calendar event to send home session reminder 2 (email) (10 days after lab session)
- Create MBB calendar event to send home session reminder 3 email (14 days after lab session)

Reminders

- Send lab session reminder 1 email (in templates - attach next steps, consent/assent)
- Send lab session reminder 2 email (in templates - attach previous and parking info)
- Confirm participant
  - Preferably by phone
  - Update lab session calendar status

2.2   Pre-Lab Session Checklist

2.2.1   Lab Session Setup - 1 Day Prior

- Create participant manila folder
- Print assent/consent forms (Check IRB expiration)
  - Parent consent
  - Assent - Child or Teen (None if under 7 years)
  - Referral consent
  - Contact list
  - DBS consent
- Print KSADS Summary Diagnostic Checklists (Write participant ID on all pages)
- Print and prepare WASI Form(Enter starting point; write participant ID on all pages)
- Print and prepare WIAT Form & Booklet (Enter starting point; Write participant ID on all pages)
- Print memory intrusion scratch paper -Enter counterbalancing order (Checklist-Lab Session Child)
- Print token economy board
- Create participant folder on Dropbox using MBB_template
- Print QR codes (from REDCap- different for every participant)
  - Child
  - Parent proxy
  - Parent self
- File QR codes on Dropbox
- Print Contact Sheet
- Print and insert Bristol Stool Scale

- Create participant info_brochure (Fill in codes)
- File participant manila folder in front section of file cabinet (Upcoming)
- Charge
    - iPads
    - iPad pencils
    - Biopac transmitters
    - VR headset (Check remote battery)
    - Audio recorders
- Label electrodes with color stickers
    - (Blue=EGG, Yellow=ECG)
- Make participant name tags
- Assemble home kit
    - Insert gut kit
    - Insert toilet hat
    - Insert oral kit
    - Insert biohazard bag
    - Insert Bristol Stool Scale
    - Label all items with participant ID (in sharpie)
    - Insert MBB info cards
- Attach FedEx slip to mailer
- Label mailer with "Exempt human specimen" (in sharpie)

2.2.2 Lab Session Setup - 1 Hour Prior

- Place in Rainbow Room
    - Consent/assent/DBS/contact on clipboard with pens
    - Consent protocol
    - Pleasant Events Checklist and Issues Checklist
    - Audio recorder #1
- Place in Bear's Den
    - Place WASI & books (2)/WIAT & card/protocol in hall testing room
- Place audio recorders in testing rooms
- Attach researcher documents to clipboards
    - Child - checklist, memory_intrusion notes, token board, gold stars
    - Parent - checklist, KSADS summary
- Turn iPads on airplane mode and WiFi off -Clear and setup KSADS on iPad (duplicate blanks)
- Photograph FedEx slip
- Pre-load questionnaires on computers
    - (Parent and Child; under 8-laminated faces)
- Pre-load physiology data templates (8)
- Move physiology station near Rainbow Room Move iPad and iPad stand near Rainbow Room Insert participant info sheet in home kit
- Assemble hair sample materials

- Prep blood spot kit

2.3 Lab Session Checklist

2.3.1 Child

- Assent
- Physiology setup
- Parent-child observation (video record)
- Drink bottle of water
- Memory intrusion (audio record)
- Halloween training
- Characters
- Halloween test
- Discrimination (run 1 of 3) *no physio
- Conditioning (sound)
- Discrimination (run 2 of 3) *no physio
- Height
- Hair sample
- Weight
- Saliva sample
- Memory generalization training (audio record)
- Extinction
- Discrimination (run 3 of 3) *no physio
- Memory generalization test
- Waist circumference
- Snack and water break
- WASI (audio record)
- WIAT (audio record)
- Blood sample
- Questionnaires
- Prize

2.3.2 Parent

- Consent
- Observation (video record)
- KSADS (audio record)
- Transfer observation video/KSADS audio recording
- Questionnaires
    - Parent Proxy or Parent Self
- Home kit issues and explained
    - Take photo of Fedex label
- Payment issued and signed

2.4   Post-Lab Session Checklist

2.4.1   Clean Up

- Tidy lab
- Disinfectant spray
- Disinfectant wipe

2.4.2   Notes

- Make note in Trello of issues to discuss (if needed) (titled: MBB### Lab Session Discussion)

2.4.3   Sample Storage

- Label and leave blood sample to dry
- Store blood sample
- Label and store hair sample
- Label and store saliva sample
- Create and assign Trello reminder to store blood sample
- Update sample storage log on Dropbox (after lab session)

2.4.4   Filing

- File consent and assent forms in filing cabinet (consent manila folder)
- File contact list in filing cabinet (contact list manila folder)
- Log participant payment in reimbursement log book
- File payment receipt photo in Dropbox payment folder
- File FedEx tracking photo in Dropbox folder

2.4.5   Data Entry

- Transfer and rename video recordings to external hard drive (delete originals)
- Transfer and rename audio recordings to external hard drive (delete originals)
- Copy behavioral task data to participant folder (raw)
- Copy physiology task data to participant folder
- Save and upload KSADS screen from iPad to participant Dropbox folder
- Save and upload any KSADS supplements from iPad to participant Dropbox folder

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2.5   Final Checklist

2.5.1   Filing

- Scan DBS consent and file in participant Dropbox folder
- Scan memory intrusion notes and file in participant Dropbox folder
- Scan KSADS summary diagnostic checklist and file in participant Dropbox folder
- Scan lab session checklists (parent & child) and file in participant Dropbox folder
- Scan WASI/WIAT (once scored) and file in participant Dropbox folder

2.5.2   Data Entry

- Enter contact list information into recruitment database
- Enter KSADS summary diagnostic checklist data to REDCap
- Enter height, weight, waist to REDCap
- Score and enter WASI data to REDCap
- Score and enter WIAT data to REDCap
- Enter memory intrusion notes to REDCap
- Enter lab session checklist - Child data to REDCap
- Enter lab session checklist - Parent data to REDCap

2.5.3   Reminders

- Home session reminder 1 email sent
- Reminder 1 phone call made
- Home session reminder 2 email sent
- Home session reminder 4 email sent

2.5.4   Home Session

- Halloween test delay
- Memory generalization test delay
- Stool kit received
- Bristol Stool Scale data received
- ASA

2.5.5   Data Entry

- Enter home session checklist data to REDCap
- Download and upload ASA data to participant Dropbox folder
- Enter Bristol Stool Scale data to REDCap

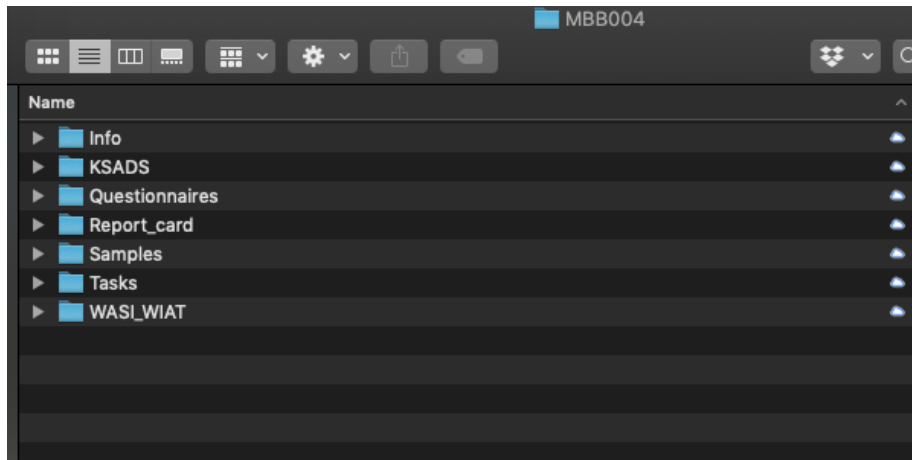### 2.5.6   Sample Storage

- Label and store stool sample

Figure 2.1:

- Update sample storage log on Dropbox (once all received)

2.5.7 Reimbursement

- Send thank you email (in templates)
- Send gift card (mail)**

2.5.8 Data Quality

- Data quality check 1
- Data quality check 2

2.5.9 Retention

- Prep report card
- Send report card email (in templates - attach report card)
- Update participant Wave 2 status

1. Open a participant data folder

2. Navigate to the report card folder and rename the template file - MBB999 to the relevant participant - and open the file

3. If an ASA nutrition report has been generated for this participant, delete page 4 of the pdf. If no ASA nutrition report has been generated, delete page 3 of the pdf.

4. Navigate to the last pge of the pdf, and fill in the scores for this participant. You can type directly on the page - it is a fillable form.
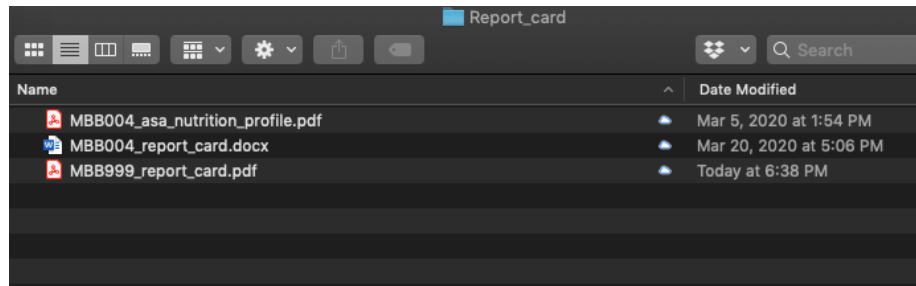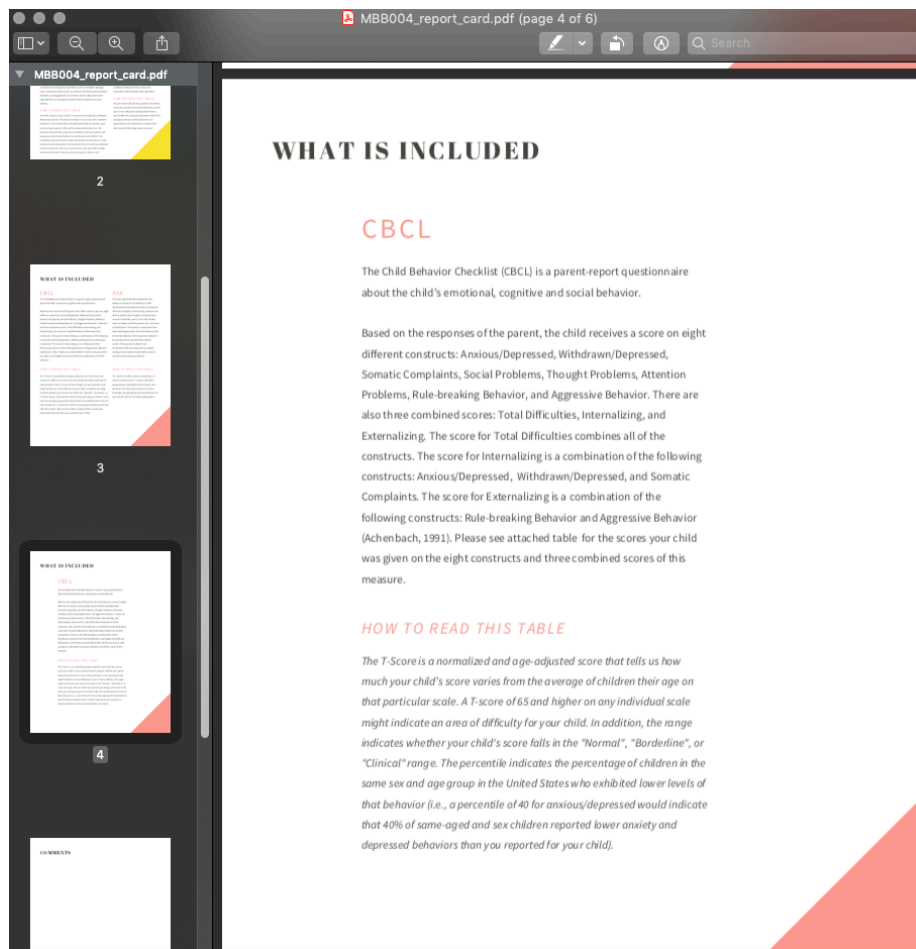
Figure 2.2:

Figure 2.3:

Figure 2.4:

5. After you have entered the data, it should look like this

6. If there are any comments, enter them on the comments page.

- For example, if any NA's are present due to less than 70% of data for that subset being available to calculate a score - note that here. Or, for example if the child was too young to receive a grade based score, you could note the aged based reading of the table here.

- If there are no comments, delete this page.

7. **Important** - Once you have completed the edits to the pdf, you must follow these steps to "lock" the data so that it is no longer editable before sending to the participant. To do so, click file/print/PDF/Save as PDF. Save the PDF to your desktop, then replace the original PDF with the desktop version.

CHILD REPORT
WAVE 1 - MIND, BRAIN, BODY STUDY

WECHSLER ABBREVIATED SCALE OF INTELLIGENCE - II	
Vocabulary T-Score	56
Matrix Reasoning T-Score	32
Estimated IQ	89
IQ Confidence Interval	83-97
Percentile	23%

WECHSLER INDIVIDUAL ACHIEVEMENT TEST-III	WORD READING	NUMERICAL OPERATIONS
Standard Score	106	91
Standard Score Confidence Interval	101-111	81-101
Percentile	66%	27%
Grade Equivalent	5.2	3.7

CHILD BEHAVIOR CHECKLIST	T-SCORE	PERCENTILE	RANGE
Anxious/Depressed	50	50%	Normal
Withdrawn/Depressed	52	58%	Normal
Somatic Complaints	50	50%	Normal
Social Problems	52	58%	Normal
Thought Problems	50	50%	Normal
Attention Problems	51	50%	Normal
Rule-breaking Behavior	55	69%	Normal
Aggressive Behavior	50	50%	Normal
Internalizing	39	14%	Normal
Externalizing	44	27%	Normal
Total Difficulties	40	16%	Normal

Figure 2.5:
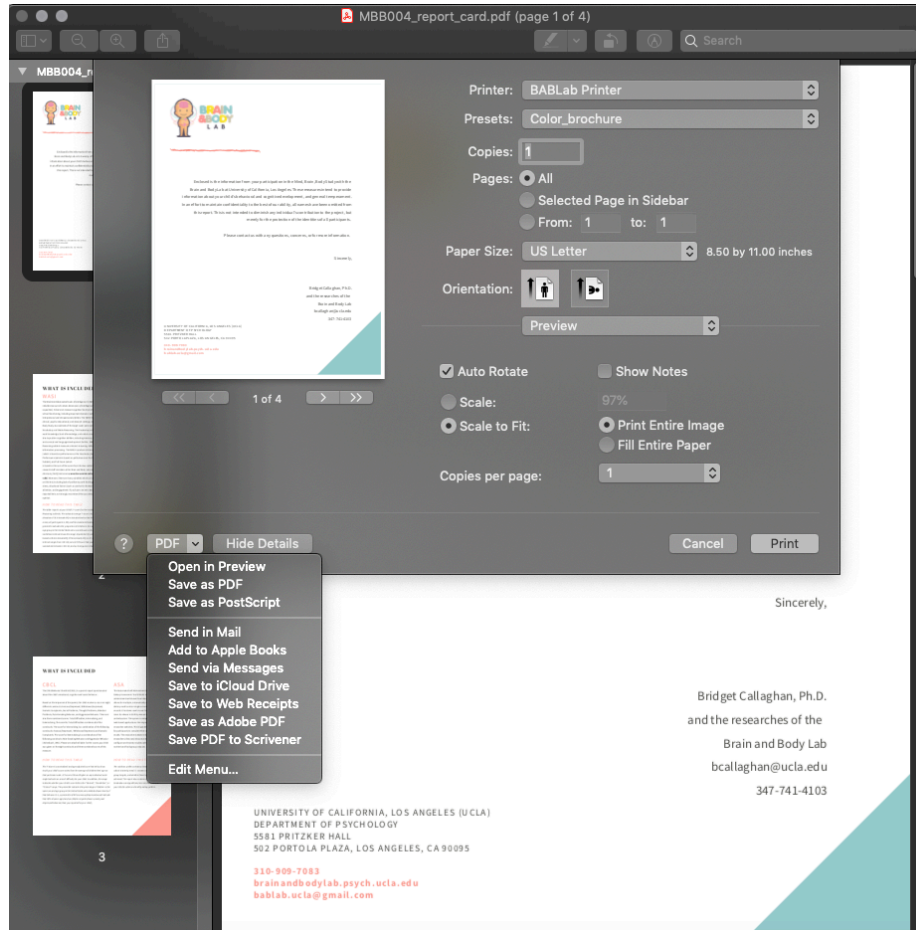
Figure 2.6:

Figure 2.7:

8. The report card is now ready to be sent to the participant.

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Chapter 3

Protocols

3.1 Consent

Once the parent and child come into the lab, seat them in the rainbow room on the couch for consenting.

Make some small talk - Ask the participant how they got here. If they have participated before in research. Offer them a bottle of water. Thank them for coming and for giving up their weekend to help science.

Tell the parent and child that the first thing you are going to do is go over all of the things they will do today, and have them sign the consent forms.

Speak to them and direct them through the whole process.

3.1.1 Things you will do in the lab

- Stick stickers on you to measure heart rate, sweat, stomach muscles.
- Sit with parent and talk about fun things and hard things (filming).
- Parent stays in room and answers more questions.
- Child goes next door to play computer games (look at pictures, watch movies). Some of the movies and pictures will be a little bit scary, others sad, others boring.
- One of the games involves a loud annoying noise, we will adjust it for you.
- You will also do some other games on paper and pencil - like puzzle and word games
- You will answer some questionnaires
- We will also measure your height, weight, and waist circumference.
- We will take three biological samples:
    - Hair - stress hormones
    - Saliva - microbiome
    - Blood - immune - wear goggles

- Do you get sick or dizzy when you see blood or hurt yourself?
- If we need to, can we prick two fingers?
- When you are done with all of that, you will get a big prize, then we will pay you and you will go home.
- You will get $45 for the work you put in today.

3.1.2   Things you will do at home

Child

- Poop sample - microbiome
- Stool scale
- Memory game - to see what you remember from lab.

Parent

- 24 hour food recall

When you complete the poop sample and the games at home, we will pay you another $20 in the form of a giftcard.

3.1.3   Things to know

You are a volunteer, which means that you do not have to do anything, or say anything that makes you uncomfortable. We would like you to try everything you can, and to do your best, but if there are things you absolutely do not want to do, just tell us, that is o.k.

We keep your participation confidential - ID number.

We want you to come in again in the future, so we will ask for some information so we can contact you in the future.

Sign consent/assent forms including DBS form and Contact Sheet

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3.2   Recruitment

3.2.1   Pre-Screening

1. Check if participant is in Recruitment Database
   - If not, add them to the Recruitment Database
2. Check if participant is in ID Drive
   - If yes, check if they have a Screener ID
   - If not, assign them a Screener ID once contact has been established based on the next available Screener ID # in REDCap and proceed with screening
   - If yes, proceed with screening under existing Screener ID in REDCap

3.2.2 Screening

1. To screen a new participant click "Add / Edit Records"
2. Click to enter a new Subject ID
   - Make sure Arm 1: Recruitment is selected
3. Type "SMBB#" (Screener ID) to create a record and hit "Enter"
   - Make sure to link the participants Screener ID and their name on the **ID Drive ONLY**
   - Before creating a new record, be sure to check the ID Drive to see if the participant already has an existing Screener ID
   - If a record exists, add a new instance of the screen instead of creating a new record
4. The screening arm contains two parts
   - The screen
   - The wave1_status
     - The wave1_status is to be updated after the first and each subsequent contact
5. Click on the radio button in the "screen" row to screen the participant
6. Click "Now" to enter today's date and time
7. Select the appropriate choice to start the phone call and follow the skip logic.
8. Follow the skip logic to the end.
   - For items without a text field, write the information down in the Recruitment database (This identifying information cannot be on REDCap)
9. Once done, select "Complete" and "Save & Exit Form"
   - The screen can be entered multiple times - for instance if there are multiple phone calls or contacts
   - It is important to keep a record of all instances of contact
10. Click the screen_status radio button
11. Select the appropriate option
    - Contact - Participant needs to be re-contacted (add Recruitment Database & ID Drive)
    - Ineligible - Participant not eligible for study
    - To Enroll - Participant to enroll (need to create subject ID, enter subject info, schedule participant, add to Recruitment Database, add to ID Drive)
    - Enrolled - Participant has been enrolled (all above have been completed)
    - To Remove - Participant wants to be removed
12. Be sure to update the screen status after each contact
    - After 3 contacts (with no response) - review (time of day, contact method, etc.)
13. If enrolled, proceed to pre-session checklist in the participant log

3.2.3   Other Screening Information

Accessing Lists

To find out where participants are in the recruitment process, there are several lists.

1. Click on "Record Status Dashboard"
2. Participants who have been enrolled will be listed in the Enrollment - Wave 1 list
3. Participants in the process of recruitment will be listed in one of the 4 Recruitment lists
   - *These lists are populated based on the individuals "Screen Status" so be sure to update after each contact!

List Types

- Contact - List of individuals who need to be contacted or re-contacted (also includes waitlist)
- Ineligible - Participants are ineligible but interested
- To Enroll - Participants who have been screened and are eligible to enroll
- To Remove - Participants who were not interested in being contacted for this or future research

3.3   Addressing Concerns

If a parent has a concern about the study before the session, send the email template:

- [MBB - CONCERNS]

Callaghan, B. L., Fields, A., Gee, D. G., Gabard-Durnam, L., Caldera, C., Humphreys, K. L., Goff, B., Flannery, J., Telzer, E. H., Shapiro, M., & Tottenham, N. (2020). Mind and gut: Associations between mood and gastrointestinal distress in children exposed to adversity. Development and Psychopathology, 32(1), 309–328. https://doi.org/10.1017/S0954579419000087

(Callaghan et al., 2020)

(Xie, 2015)

(Callaghan et al., 2020)

Bibliography

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Xie, Y. (2015). *Dynamic Documents with R and knitr*. Chapman and Hall/CRC, Boca Raton, Florida, 2nd edition. ISBN 978-1498716963.