

BEFORE AND AFTER: INTEGRATING HEALTH LITERACY INTO STUDY MATERIALS



Health Literacy in Clinical Research

- This presentation shows some examples of how health literacy best practices can be integrated into:
 - Clinical research recruitment flyers
 - Study medication instructions

....and also gives you a chance to practice your own plain language writing skills!



Health Literacy Best Practices

- Health literacy best practices can be integrated into the clinical trial life cycle when study materials are developed for potential, enrolled and past study participants.
- Health literacy best practices include:
 - Writing and speaking in plain language and a conversational tone
 - Presenting numeric information in simplified ways
 - Using design techniques to present information clearly
 - Formatting information in ways that are easier to read and follow



Recruitment Flyer

A recruitment flyer can help people understand the research study.

Use health literacy best practices to develop introductory information like this one on joining COVID-19 trials.

Scroll through to see some health literacy best practices in action.

I AM HEALTHY:
Should I Join a COVID-19 Research Study?

People who do not have COVID-19 can help researchers learn more about the disease.

A research study:

- collects new information about health and disease.
- tries to answer new questions that researchers have.
- needs volunteers to sign up.

COVID-19:

- is a new disease caused by a type of virus called coronavirus.
- may cause some people to have symptoms like cough, fever, weakness, muscle and other pains, and breathing problems.
- can be mild, but it can also make some people very sick, and may lead to death.

Why are there research studies about COVID-19 right now?

COVID-19 is a new disease, so it is important to understand more about:

- How the virus spreads.
- Why some people get very sick, and some people do not.
- Which treatments work best, and if they work for everyone.
- How to prevent new infections.

What should I ask the research team before joining a COVID-19 research study?

- ✓ Why is the study being done?
- ✓ What will happen if I agree to join?
- ✓ Could the study help me? Could it help others?
- ✓ Could the study cause risks to me?
- ✓ Do I have to pay money to be in the study?
- ✓ Will I be paid to be in the study?
- ✓ How will my personal information be protected?
- ✓ How long will the study last?
- ✓ Can I leave the study at any time?
- ✓ What will happen if I get hurt in the study?
- ✓ Who should I call with questions about the study?
- ✓ Will I get to see the study results?

What else should I know about being in a COVID-19 research study?

- You can talk to people you trust about whether to join the study.
- You can change your mind at any time.

Being in a COVID-19 research study is your choice.

More can be learned about COVID-19 if you join a research study.

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER OF BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

Thank you for thinking about joining a COVID-19 research study for healthy volunteers. Please ask the research team ANY questions you have.

HARVARD CATALYST
Harvard Clinical & Translational Science Center



Headers are brief and clear.

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Plenty of white space makes the info easier to read.

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Bullets break-up information into smaller chunks that are easier to understand.



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More can be learned about COVID-19 if you join a research study.

Active voice is easier to read and understand.

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Images and icons engage your audience. People especially like seeing other people and faces.



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Questions draw the reader into the materials.



Thank you for thinking about joining a COVID-19 research study for healthy volunteers. Please ask the research team ANY questions you have.



Medication Instructions

Dense, text-heavy instructions can be very difficult for people to read and follow.

Health literacy best practices help improve study medication instructions.

Scroll through to see some health literacy best practices in action.

Injection Guide for Study Drug or Placebo Panel A (Days 1-5) and Panel B (Days 6-10)

Instructions for Use

Study Drug or Placebo Injection

Each vial contains 1 mL of study drug or matching placebo. The volume removed from the vial determines the dose administered. The study staff will tell you how much to inject from each vial.

Important Information

- › **Refrigerate kit box: Do Not Freeze.**
- › **Vials should only be used one time.**
- › **Only uncap the vials that you are preparing to inject.**
- › **Only inject the volume instructed by study staff. Do not inject the entire contents of either vial.**
- › **Always use a new site-provided syringe/needle for each injection.**

Step 1: Prepare Vials

- Remove 2 vials from the kit box and return kit box to the refrigerator.
- Allow vials to come to room temperature for at least 15 minutes.
- Vials should then be inverted a minimum of three times.
- Wash your hands with soap and water.

Step 2: Prepare Syringe

- Remove the cap from one of the vials and wipe the top of the vial with an alcohol swab.
- Open a new syringe and needle.
- By pulling back on the plunger, draw air into the syringe up to the mark of the volume to be injected and then slowly inject the air into the vial.
- Keep the needle in the vial and turn the vial upside down. Make sure that the needle tip is well below the surface of the liquid in the vial.
- With the tip of the needle in the liquid, pull slowly back on the plunger to get the right volume into the syringe.
- Check the syringe for air bubbles. If there are bubbles, hold both the vial and syringe in one hand, and tap the syringe with your other hand. The bubbles will float to the top. Push the bubbles back into the vial, then pull back to get the right volume of study drug/placebo.
- When there are no bubbles, take the syringe out of the vial. Put the syringe down carefully so the needle does not touch anything.

Step 3: Injection

- Clean an injection site that is about 2-3 inches away from your belly button on your abdomen with a new alcohol swab. Let dry thoroughly.
- Hold the syringe in the hand that you will use to inject study drug. Use the other hand to pinch a fold of skin at the cleaned injection site.
- Use the injection technique shown to you by the study staff.
- After the needle is inserted and while pinching the skin, pull the plunger back slightly. If no blood appears, steadily push the plunger all the way down until the study drug is injected. **Note:** If blood enters the syringe, remove the syringe, clean and prepare another spot on your abdomen and using the same syringe/needle, inject the product.
- Leave the syringe in place for about 6 seconds after injecting (the pinch may be released) and remove. After the needle is removed, you can apply light pressure with clean gauze or cotton ball but, do not rub the site.
- Place used syringe/needle (do not re-cap the syringe) in a sharps disposal container provided by the site.



How to give yourself the study medicine

Panel A (Days 1-5) and Panel B (Days 6-10)

All text left justified
which is easier to
read.

Study medicine

Each bottle holds 1 mL of active drug or placebo.

The study staff will tell you how much medicine to use each time (this is called your dose). Only give yourself the dose the study staff told you. Do not use all the medicine in the bottle.

The study staff will tell you how much to inject from each bottle.

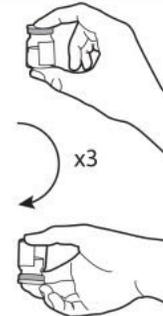
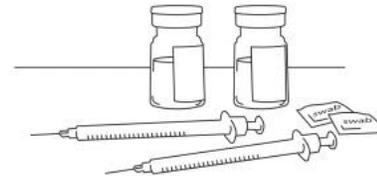
Important safety information

- Refrigerate the kit box – Do not freeze.
- Only use each bottle 1 time.
- Use a new syringe and needle each time.
- Only uncap the bottles when you use them.

Steps to give yourself the study medicine

Get ready

1. Gather your supplies:
 - 2 syringes
 - 2 bottles of medicine
 - 2 alcohol swabs
2. Take out 2 bottles from the kit box and put the kit box back in the refrigerator.
 - Let the bottles sit on the counter for at least 15 minutes to get to room temperature.
 - Turn the bottles upside down and then right side up at least 3 times.
3. Wash your hands with soap and water.



How to give yourself the study medicine

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Information broken into chunks that are easier to read and manage.

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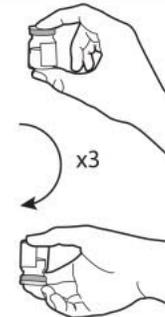
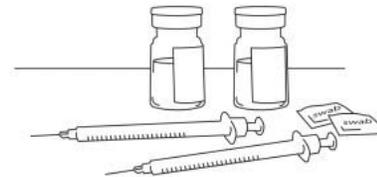
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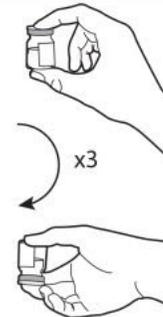
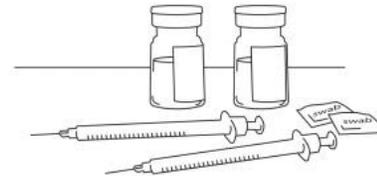
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Different sections shaded with different colors to break-up content.



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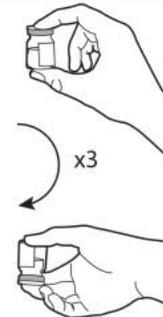
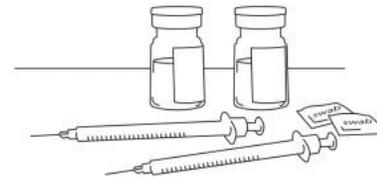
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Informative headings that are easy to spot.



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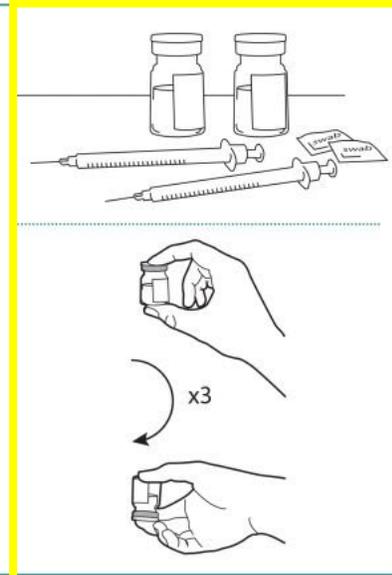
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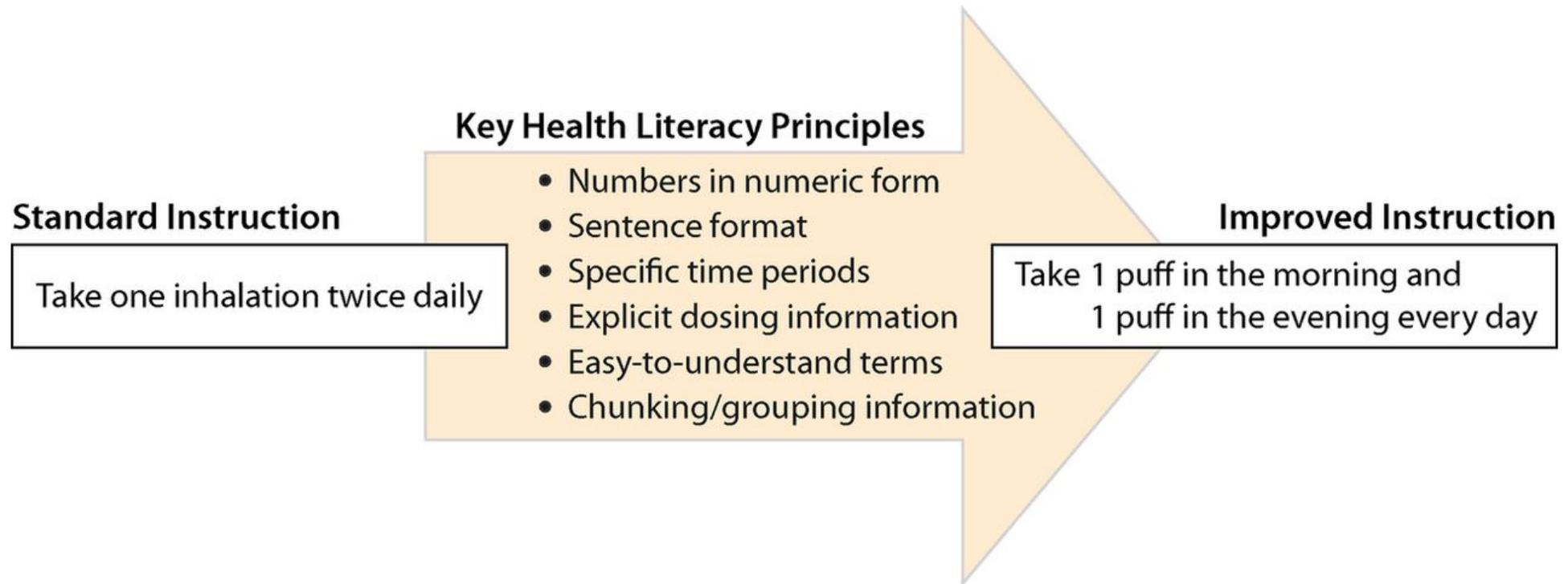
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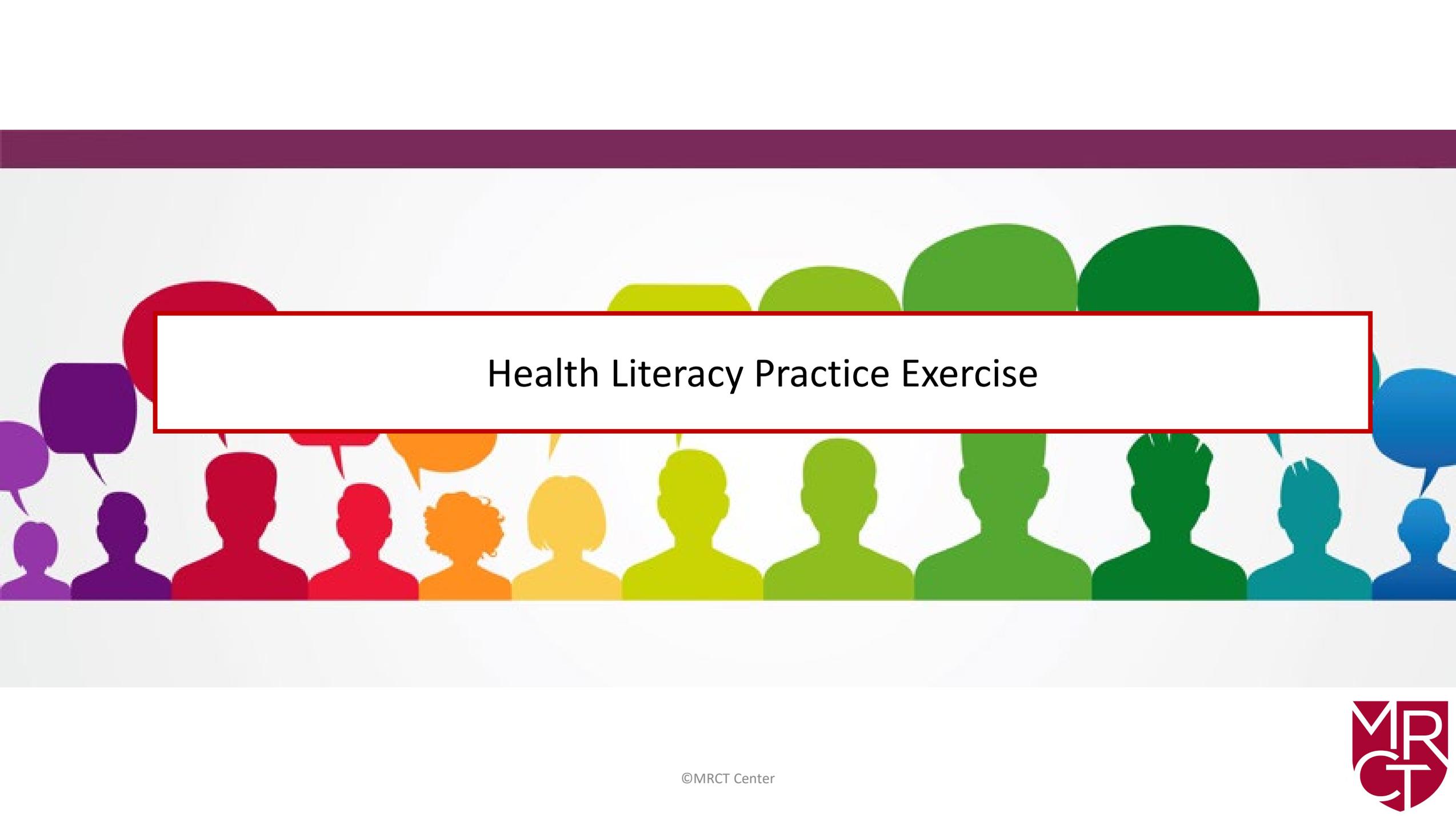


Graphics added to make instructions easier to follow.

Bonus health literacy tips!



<https://bmjopen.bmj.com/content/4/1/e003699>



Health Literacy Practice Exercise

Instructions

- 1) Review the original text for each of the three examples.
- 2) Simplify each example using some of the health literacy best practices discussed previously and at www.mrctcenter.org/health-literacy
- 3) Reflect:
 - What changes did you make to the text?
 - What health literacy best practices did you apply?



Example 1: Study Recruitment Flyer Text

Elderly subjects with hypertension are being sought to enroll in a randomized double-blind trial of a new anti-hypertensive medication as compared to the standard of care.

Please rewrite this text using health literacy best practices.

What changes would you make?

Please describe.



Example 2: Study Medication Instructions

Study subjects will be asked to take 2 tablets three times a day for 7 days, then take 2 tablets two times a day for another 7 days.

Please rewrite this text using health literacy best practices.

What changes would you make?

Please describe.



Example 3: Introductory Consent Information

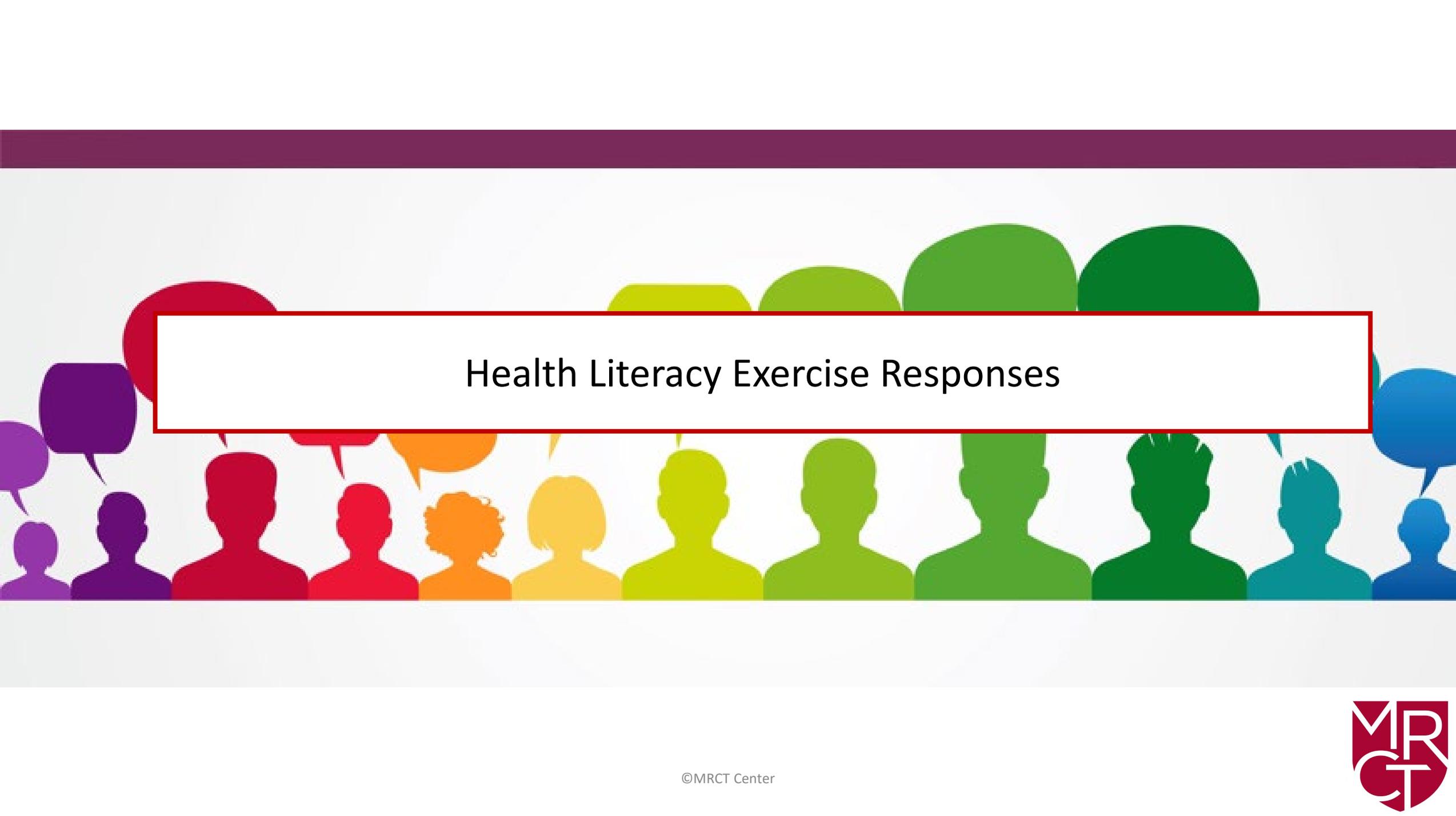
We are conducting a research study in order to determine the current status of the psychosocial and health problems due to SARS-CoV-2 (COVID-19) faced within our patient community and to implement a brief online intervention based on Cognitive Behavior Therapy techniques and measure its effect. Study subjects will be assessed by completing a battery of psychological tests at various timepoints throughout the study.

Please rewrite this text using health literacy best practices.

What changes would you make?

Please describe.





Health Literacy Exercise Responses

Example 1: Study Recruitment Flyer Text

Before:

Elderly subjects with hypertension are being sought to enroll in a randomized double-blind trial of a new anti-hypertensive medication as compared to the standard of care.

After:

Researchers are looking for people who are older than 74 years of age and have high blood pressure to join a study. The study will test whether taking a new medicine will lower blood pressure as compared to the usual treatment. A computer will be used to place participants into one study group or the other.



Example 2: Study Medication Instructions

Before:

Study subjects will be asked to take two tablets three times a day for seven days, then take two tablets two times a day for another seven days.

After:

For days 1 through 7:

Take 2 tablets in the morning; 2 tablets around lunch time; and 2 tablets in the evening, every day.

For days 8 through 14:

Take 2 tablets in the morning, and another 2 tablets in the evening every day .

DAY / DIA			
Time/Hora:			
Monday / Lunes			
Tuesday / Martes			
Wednesday / Miércoles			
Thursday / Jueves			
Friday / Viernes			
Saturday / Sábado			
Sunday / Domingo			
Monday / Lunes			
Tuesday / Martes			
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Saturday / Sábado			
Sunday / Domingo			

Consider adding a schedule!

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After:

In this research study we want to learn more about what kinds of health and wellness problems people are having due to COVID-19.

We also want to know whether a few short mental health lessons offered on the internet could help with any of these problems.

We will use some surveys during the study to find out if people in the study start to feel better after viewing the lessons.



Thanks for taking the time to practice putting health literacy into action!

Find more resources at www.mrctcenter.org/health-literacy

