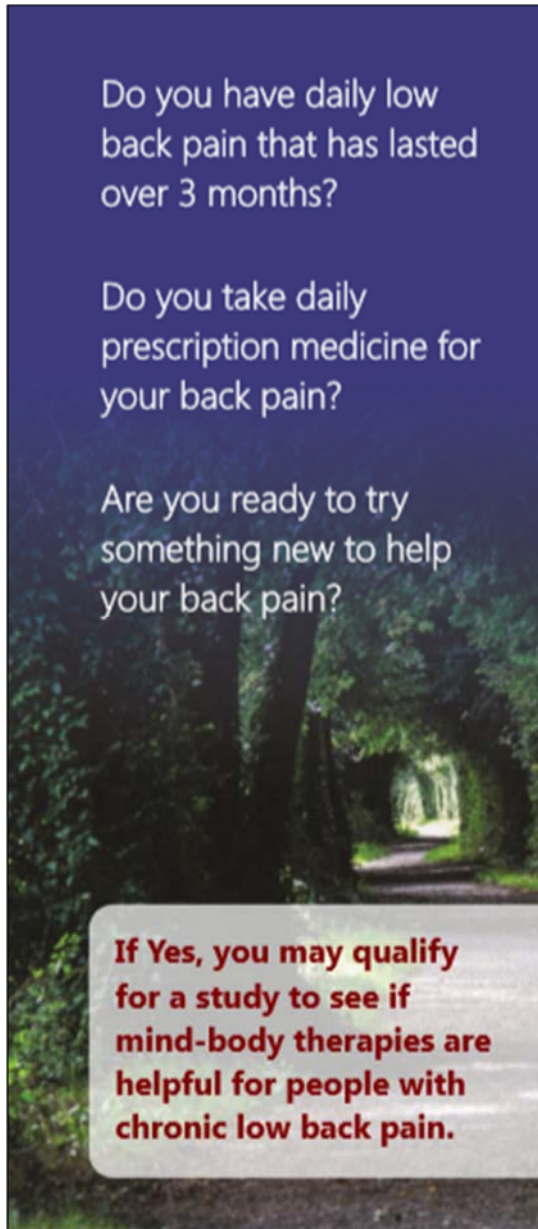


Example of Stakeholder Impact: Recruitment Brochure

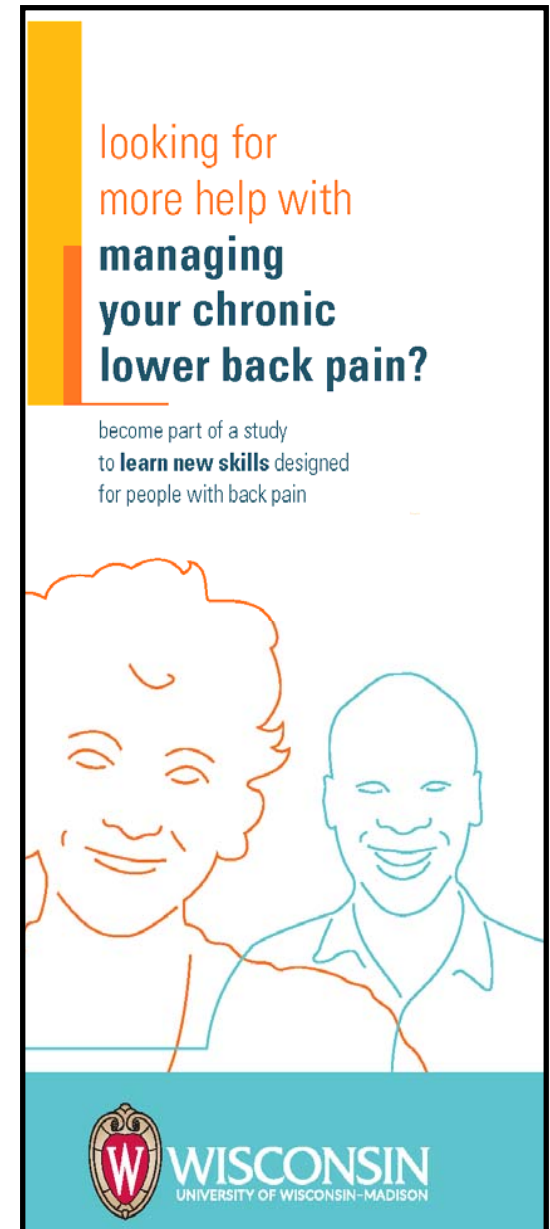
Before



PFAC feedback on recruitment brochure:

- Cover image is dark, depressing, has nothing to do with CLBP
- University logo needed to add legitimacy
- Too many words
- Text on blue background is difficult to read
- “Mind-body” raises questions and concerns

After



Before

When and where will the study sessions be held?

The study will start in June 2017.

All study sessions will be conducted in [Madison/Salt Lake City/Boston] at [name of hospital/clinic site]. [Add in general time of day/day of week if it will be constant.]

Will I be paid?

Yes, you will be compensated up to \$240 for your study participation;

The mind-body therapies are provided free of charge.

This study is a collaborative effort between researchers and clinicians at the University of Wisconsin-Madison (Madison, WI), University of Utah (Salt Lake City, UT) and Brigham and Women's Hospital at Harvard University (Boston, MA).



Mind Body Therapies for Back Pain Study is funded by the Patient-Centered Outcomes Research Institute (PCORI).

Cover photo: Mark Robinson / Creative Commons Attribution-NonCommercial 2.0 Generic (goo.gl/FKZ010)

Do you have daily low back pain that has lasted over 3 months?

Do you take daily prescription medicine for your back pain?

Are you ready to try something new to help your back pain?

If Yes, you may qualify for a study to see if mind-body therapies are helpful for people with chronic low back pain.

Mind-Body Therapies for Back Pain

What is this study about?

We want to see if mind-body therapies can help people with chronic low back pain:

- **Mindfulness Meditation** trains the mind to pay attention to thoughts, feelings, and body sensations as they occur.
- **Cognitive Behavioral Therapy** trains the mind to engage in healthy thinking and mental strategies.

Both therapies can help people manage health problems, including pain. Study participants will be randomly selected to receive one of these therapies (like flipping a coin).

Is this study right for me?

This study might be a good fit for you if you:

- Are over 21 years old;
- Experience daily low back pain for at least 3 months;
- Have been prescribed daily opioid (narcotic) medicine (like Vicodin®, Percocet®, oxycodone, or morphine) for your back pain;
- Are willing to attend 8 weekly sessions, practice recommended strategies daily, and complete follow-up surveys and tasks.

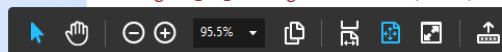
What would I need to do as a study participant?

- Attend eight weekly classes that teach strategies for addressing pain using Mindfulness Meditation or Cognitive Behavioral Therapy;
- Practice taught strategies daily;
- Complete two in-person visits to answer survey questions;
- Complete three additional survey sets either online or by phone.

Total participation time lasts one year.

How can I learn more about the study?

For more information and to find out if you qualify for this study, please visit our website: www.great_url_here.org or contact Name, Phone, E-mail



where will the study sessions be held?

The study will be held in three cities:
Madison, Salt Lake City and Boston.
Please contact us for details on the location and schedule.

how can I learn more about the study?

To find out more about this study, please contact:
Madison STAMP Study Team
STAMPstudy@fammed.wisc.edu
608-212-6902
or visit www.STAMPstudy.org

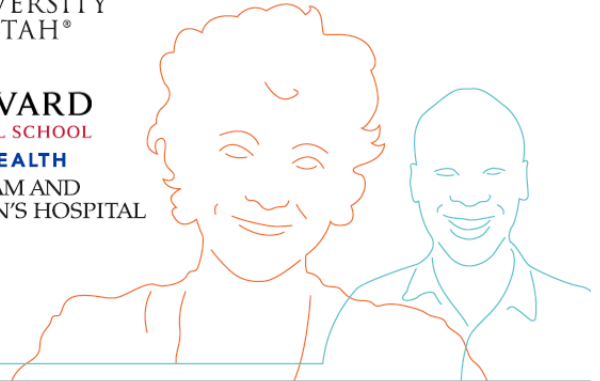


This study is a collaborative effort among the University of Wisconsin (Madison, WI), University of Utah (Salt Lake City, UT) and Brigham and Women's Hospital, Harvard Medical School (Boston, MA).



looking for more help with managing your chronic lower back pain?

become part of a study to **learn new skills** designed for people with back pain



The STAMP (Strategies to Assist with Management of Pain) Study is funded by the Patient-Centered Outcomes Research Institute (PCORI).



STAMP

strategies to assist with management of pain

what is the STAMP study about?

You can be part of an 8-week training program to learn one of two methods that may **help you better cope with chronic lower back pain and live a more fulfilling life.**

One method will teach you to reduce your negative reactions to pain. The other will teach you how to change your thoughts and feelings associated with pain. Your study involvement would be in addition to your medical care.

You will not need to change any of your current treatments or medications.

is this study right for me?

This study may be a good fit if you:

- Are interested in learning new methods designed to help manage your back pain
- Agree to be assigned in a random way (like by flipping a coin) to learn one of two methods to help manage pain
- Are 21 or older
- Experience daily lower back pain for at least 3 months
- Are prescribed daily pain medication for your back pain (like Vicodin®, Percocet®, oxycodone, or morphine)



what would I need to do as a study participant?

- Complete an 8-week training program of weekly 2-hour sessions in your local city to learn one of the two new methods taught in the study
- Practice the pain management method at home daily
- Be available for two in person visits (at the beginning and the end of the study)
- Complete brief online or phone surveys during this one year study

will I be paid?

Yes, you will be compensated for your time and participation, and the therapies offered in the study will be provided free of charge.

Example of Stakeholder Impact: Recruitment mailing response card

Before

OPT OUT CARD

No, I do not wish to participate in the STAMP study.

If you promptly return this pre-paid card, you will not be contacted by the research team.

Otherwise we will try to contact you in the next 2-3 weeks.

Problem

- The research team noticed receiving more “opt-out” cards than expected and asked if the cards could be confusing and people are mailing them back wanting to be contacted.

PFAC feedback on response card:

- The card might be confusing, as the term “opt-out” is not common language. People may be sending it back when they want to be contacted.
- They recommended we change it to “Response Cards” and have check-box options for both “Yes, please contact me with more information” and “No, I am not interested”.
- They also recommend changing the color of the card away from bright yellow to white or light blue, so the card will not draw too much attention.

After

Response Card

Yes, I would like to learn more about the STAMP Study and I would like a team member to call or email me.

Best time to call: _____

No, I do not wish to participate in the STAMP study. Please do not call or email me.

If we do not receive this card back, we will try to contact you.

Example of Stakeholder Impact: Recruitment letter

PFAC feedback on recruitment letter:

- Letter needs to be much shorter, more compelling, and warmer.
- Includes too much detail that could be overwhelming. Details can be better explained on the phone
- Appeal to people's sense of altruism (e.g., that this study will help address the opioid epidemic).
- Suggested words and phrasing: "understand how to manage pain", "more control over pain", "tools/strategies to control pain", "cope", "learn"

Before

Dear «first name» «last name»:

I am Dr. Aleksandra Zgierska. I am a physician and researcher at the University of Wisconsin-Madison. I am writing to invite you to participate in a new study called "*Strategies to Assist with Management of Pain*" or *STAMP*. I hope this study could be helpful to you.

We are looking for individuals with chronic lower back pain who take prescription pain medications and are willing to try something new, alongside their current treatment, to help manage pain. You are being contacted because you are a patient at UW Health. The UW Health clinicians are collaborating with my team and me on this research, and thought this study may be of interest to you.

We are doing the STAMP study to learn if one of two methods can help people with chronic lower back pain. One method will teach you to reduce your negative reactions to pain; the other will teach you how to change your thoughts and feelings associated with pain. People in our study will be randomly selected (like by flipping a coin) to receive a free training in one of these two methods.

The study involves the following activities:

- 1) Two in person visits in Madison at the beginning of the study and 1 year later to collect data on pain, its impact and related treatments.
- 2) A free 8-week training (eight weekly, two-hour group classes) in one of the two methods.
- 3) Three brief sets of surveys online or by phone every 3 months.
- 4) Brief check-ins (online or by phone) every 2-4 weeks to see how you are doing.
- 5) Daily practice of the taught skills at home.

This study will last one year.

- You will be paid up to \$240 if you complete all study activities.
- Participating in this study will not affect your usual health care. During the study, you will continue to see your regular providers and continue medications and other treatments as recommended by them.

The attached materials explain the STAMP study in more detail. You can also check the study website at www.STAMPstudy.org for more information. If you know others who may be interested in the study, please feel free to share this information.

If you have questions or are interested in the study, please either contact our research team (email: STAMPstudy@fammed.wisc.edu; phone: 608-212-6902) or wait for a phone call from us; unless we hear from you otherwise, a team member will call you in the next 2-3 weeks to talk about this study. It may be helpful for you if you have the study materials available during this call. If you do NOT wish us to call you, please mail back the enclosed prepaid OPT-OUT card.

Thank you for considering the study! Together we can learn new ways to help people with chronic pain!

Sincerely,

Aleksandra Zgierska, MD, PhD

After

Dear «first name» «last name»:

My name is Dr. Aleksandra Zgierska and I'm a physician and researcher at the University of Wisconsin-Madison. I care for many patients with chronic pain and am passionate about finding better ways to help people manage their pain. That's why I'm writing to invite you to participate in a new research study called "*Strategies to Assist with Management of Pain*" or *STAMP*. I hope this study will be helpful to you and also improve our understanding of how to help people with pain.

We're looking for people with **chronic lower back pain** who take daily medications for it and are willing to learn something new to help with back pain. Please know that you would not have to change your current treatments or medications to participate; the study is meant to give you additional tools to help manage pain.

The study will last one year and involves the following activities:

- Two, approximately 60 minute in person visits: one at the beginning of the study and another 1 year later.
- An 8-week program in one of two pain treatment methods (2-hour sessions once a week)
- Three 30-60 minute follow-up surveys once every 3 months
- Very brief, 5-10 minute check-ins, approximately monthly
- Daily home practice of the pain management methods you learn
- Earn up to \$240 if you complete all study activities

The enclosed brochure explains the STAMP study in more detail. You can also go to the study website at www.STAMPstudy.org.

If you have questions or are interested in learning more about the study please contact our research team by:

- Phone: 608-212-6902,
- Email: STAMPstudy@fammed.wisc.edu or
- Mail back the enclosed pre-paid Response Card

Thank you for considering! **Together we can learn new ways to help people with chronic back pain!**

Sincerely,

Aleksandra Zgierska, MD, PhD

Example of Stakeholder Impact: Voicemail phone script for recruitment calls

Before

Hello, this message is for [NAME]. My name is [RESEARCH COORDINATOR NAME] and I'm a researcher from [SITE NAME]. I'm calling to follow up on a letter recently sent to you inviting you to participate in a research study. I'm hoping to talk with you briefly about it. Please call me back at [SITE-SPECIFIC PHONE NUMBER]. If I do not hear from you, I will try to call you later from this number. Thank you very much!

Problem

- The research team noticed very few people calling back in response to research coordinators leaving voice mail messages

PFAC feedback on voicemail script:

- Overall, make it more conversational and less formal
- Suggested the caller should not identify themselves as a "researcher"
- Suggested the sentence "I'm calling you about a paid research opportunity you might be interested in"
- Replace the phrase "hoping to talk to you" with "I'm looking forward to talking with you"
- Suggested saying "you may have received a letter from us", as the person may or may not have seen the mailing
- Give the call back phone number twice, making sure to say the number slowly
- End the message with a warm phrase such as "Thank you for your time" and/or "have a great day"

After

Hi, [NAME]. My name is [RESEARCH COORDINATOR FULL NAME] I'm calling from [SITE NAME] about participating in a paid research opportunity. You may have received a letter in the mail from us about this study, and I'm looking forward to talking with you about it. Please call me back at [SITE-SPECIFIC PHONE NUMBER]. Again my name is [RESEARCH COORDINATOR FIRST NAME] at [SITE-SPECIFIC PHONE NUMBER]. Thank you for your time and have a good day!

Example of Stakeholder Impact: In-depth interview guide

SAC selected feedback on physical function section of interview guide:

- Change the wording to: “Comparing those surveys over time, it looks like your function has increased over the last year”.
- Avoid the term “function”; it is too clinical.
- Be consistent with using the term “daily activities”.
- Add questions about what specifically improved for them, which will tease out what is most important to them. For example perhaps their sleep has improved but not walking, etc.
- Members discussed if it would be helpful or not to include examples of everyday activities in the question, or if it that would put people in a mindset to only think about the things listed. One suggestion was to say, “activities you do every day” and not list any examples.. Others felt that having some examples, (but making it clear they were just some of the potential activities), would be helpful.

Before

SECTION 3. FUNCTIONING

3.1 Again, according to the responses you gave us in the questionnaires about your everyday life activities at the beginning of the study, one year ago, and now at the end of the study, it looks like you have had improvements in your ability to carry out at least some of everyday things like lifting, walking, sitting, sleeping, and traveling, is this correct?

YES ___

NO ___ (Can you help me understand this better – your everyday life activities appear to be improved but you don’t think this is the case?)

3.2 What helped you increase your ability to carry out everyday life activities?

FOLLOW-UP 1: Is there anything else that helped you increase your ability to carry out everyday life activities?

FOLLOW-UP 2: Did MBT/CBT help you in any way to increase your ability to carry out everyday life activities?

IF YES: How did MBT/CBT help you increase your ability to carry out everyday life activities?

FOLLOW-UP 3: Are there any other ways that MBT/CBT helped you increase your ability to carry out everyday life activities?

IF YES: How else did MBT/CBT help you increase your ability to carry out everyday life activities?

FOLLOW-UP 4: Did MBT/CBT give you any tools or skills that helped you increase your ability to carry out everyday life activities?

IF YES: What MBT/CBT tools or skills helped you increase your ability to carry out everyday life activities?

IF YES: How did these MBT/CBT tools or skills help you increase your ability to carry out everyday life activities?

3.3 Of all the things that helped you increase your ability to carry out everyday life activities over the past year – whether part of the MBT/CBT training or outside of it – what was the most helpful?

3.4 What advice would you give others in your situation to help them increase their ability to carry out everyday life activities?

After

SECTION 3. FUNCTIONING

3.1 My next questions are about your ability to do your daily activities. Daily activities are the things we normally do, such as bathing, dressing, walking, preparing meals, taking care of yourself or your household, or interacting with others. These are just a few examples; there are many other types of daily activity. Please think about your own daily activities for the following questions.

Comparing, again, the surveys you filled out over the past 12 months or so, it looks like your ability to do at least some of your daily activities has improved, is that correct?

__YES GO TO 3.2

__NO Can you help me understand better – your survey responses show improvement in your daily activities, but you don’t think that is the case? GO TO 4.1

3.2 What daily activities have improved for you?

3.3 What has helped you improve your ability to do your daily activities?

3.4 Is there anything else that has helped you improve your ability to do your daily activities?

__YES GO TO 3.5 __NO GO TO 3.6

3.5 What else (has helped you improve your ability to do your daily activities)?

__ANYTHING OTHER THAN MM/CBT - GO TO 3.6

__MM/CBT - GO TO 3.7

3.6 Has MM/CBT helped you improve your ability to do your daily activities in any way?

__YES GO TO 3.7 __NO GO TO 3.8

3.7 How (has MM/CBT helped you improve your ability to do your daily activities)?

3.8 [IF >1, ASK; ELSE GO TO 3.9] Of all the things that have helped you improve your ability to do your daily activities over the past 12 months – whether part of the MM/CBT training or outside of it – what has been the most helpful?

3.9 Have you ever experienced any mood problems, stress, or anxiety about your ability to do your daily activities?

__YES GO TO 3.10 __NO GO TO 3.12

3.10 Has MM/CBT in any way affected your mood, stress, or anxiety about your ability to do your daily activities?

__YES GO TO 3.11 __NO GO TO 3.12

3.11 How has MM/CBT affected your mood, stress, or anxiety about your ability to do your daily activities?

PROBE: How has MM/CBT affected the way you think or feel about your ability to do your daily activities?

3.12 What advice would you give others in your situation to help them improve their ability to do daily activities?