Study Title: The Positive Piggy Bank - A Positive Activities Intervention for Improving Functional Status in Patients with Back Pain

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NCT: NCT02476812

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

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UNIVERSITY OF MICHIGAN

CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: The Positive Piggy Bank – A Positive Activities Intervention for Improving Functional Status in Patients with Back Pain

1.2 Company or agency sponsoring the study: Department of Anesthesiology, University of Michigan

1.3 Names, degrees, and affiliations of the researchers conducting the study:

Afton Hassett, PsyD, Associate Research Scientist, Department of Anesthesiology, University of Michigan
Chad Brummett, MD, Assistant Professor, Department of Anesthesiology, University of Michigan
Jenna Goesling, PhD, Assistant Professor, Department of Anesthesiology, University of Michigan
Stephanie Moser, PhD, Data Analyst, Department of Anesthesiology, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

The purpose of this study is to evaluate the effectiveness of a new non-drug treatment for improving functional status in people with back pain.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. This study will not affect your care in any way.

3.1 Who can take part in this study?

Men and women between the ages of 18 and 80, diagnosed with back pain and who are undergoing an epidural steroid injection can take part in this study. Patients should have no plans of changing medications or interventions during the 30 day period.

3.2 How many people (subjects) are expected to take part in this study?

We expect to enroll 200 patients to take part in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to take part in this study and sign this consent form, you will first complete some questionnaires that ask about a variety of topics including pain, mood, and your day-to-day activities. Then, if you continue to meet study criteria, you will be randomly assigned to one of two groups. One group will get the positive activities intervention immediately (Positive Piggy Bank), while the other group will serve as the control group (wait for 90 days before having the option to do the Positive Piggy Bank intervention). Both groups will be asked to complete

questionnaires on the first visit and by mail 30 and 90 days later. Study staff will make phone calls to alert you when the study questionnaires are being sent to you and to remind you to send them back. After the 90 days, individuals assigned to the control group will then be offered the opportunity to take part in the positive activities intervention. If you are in the control group and choose to do the Positive Piggy Bank activity, you will be asked to return to the study site to receive your materials and instructions and after 30 days complete one more set of questionnaires by mail.

If you are randomized to the Positive Piggy Bank group, you will get an overview of the intervention and receive instructions about how to keep a Positive Piggy Bank over the next 30 days. You will choose your piggy bank and other supplies that you will need for this positive activity. The research assistant will contact you within 72 hours of beginning the study to answer your questions. You will also be contacted by phone 30 days after you started the intervention. You will be asked to return the paper currency slips (slips of paper describing positive things that happened each day) along with the first set of follow up questionnaires. The paper currency slips will be photocopied and sent back to you soon after we receive them. The last set of questionnaires is to be completed 60 days after you completed the Positive Piggy Bank and then returned by mail. Follow up questionnaires must be completed within 10 days of the 30 or 90 day date.

4.2 How much of my time will be needed to take part in this study?

The day of your clinic visit the study orientation will take approximately 45 minutes. If you are in the intervention group, you will complete 30 days of recalling and noting positive events. Each day's activities will take approximately 5-10 minutes. Also, completing the two packets of questionnaires by mail should take less than 45 minutes to complete each packet.

4.3 When will my participation in the study be over?

If you are in the Positive Piggy Bank group, your participation will last 90 days (concludes after the 2-month follow-up assessment). If you are in the control group, your participation could last another 30 days if you choose to do the Positive Piggy Bank intervention after the 90 day waiting period. You would also have to return for another visit to pick up you piggy bank and related supplies.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

- *Self-report Questionnaires:* There is a possibility of discomfort associated with being asked personal questions about health history, symptoms, or emotional feelings. You may decline to answer any question on the questionnaires that may make you uncomfortable. Although there is a very low risk that this will happen, study personnel will be nearby to offer support to you if you become distressed. If you experience severe distress, you may be referred to the appropriate mental healthcare providers.
- *Changes in clinical care:* The risk that participating in the study might somehow influence clinical decisions is unlikely. Your physician will not be involved in any subsequent part of recruitment or data collection.
- *Breach of Confidentiality:* Personal information about you will be collected during the course of this study using questionnaires. These will be number coded and kept separate from any information that could identify you. All of your information will be locked in a file cabinet in a secure research office.

The researchers will try to minimize these risks by being available for questions regarding any issues that are related to the study.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. All information learned from this study could help medical persons better manage and treat patient with chronic pain.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Your health care provider will discuss with you all other options.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No, there will be no harm to you.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

Yes, you will be paid $20 every time you complete study questionnaires. You will complete questionnaires three times (initial clinic visit, 30-day follow up, and 90-day follow up) for a total of $60. You may also choose to keep the piggy bank if you complete the Positive Piggy Bank intervention. If you are in the wait list control group, you may also receive $20 for coming back to the center to pick up your supplies and another $20 for completing one last set of questionnaires by mail. If you sign a consent form, but are found to be ineligible to participate, you will receive a $10 check for your time and effort. The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

8.3 Who could profit or financially benefit from the study results?

At this time, nobody will profit financially from the study results.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

Research records will be kept in a database at the University of Michigan that is password protected and only available to research staff.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- Your AIDS/HIV status

- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are. A description of this clinical trial is available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared

with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:	Afton Hassett
Mailing Address:	24 Frank Lloyd Wright Drive, Lobby M Ann Arbor, MI 48106
Telephone:	734-998-6939
Study Coordinator:	Joseph Long
Mailing Address:	325 E Eisenhower Pkwy Ste 100 Ann Arbor, MI 48108
Telephone:	734-763-5226

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111. *When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

- Other (specify): Positive Piggy Bank, study calendar, and slips of paper for 30 day intervention.

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____