**Appendix 1: Study 1 Plain Language Template**

**A Pilot Study of Acupuncture Treatment for Swallowing Problems in Head and Neck Cancer Patients**

***Thank you for your interest in this study.***

Here we describe the results of this study.

This summary was completed in March 2016. Newer information since this summary was written may now exist. This summary includes only results from one single study. Other studies may find different results.

**This study asked whether acupuncture affected people with head and neck cancer who had difficulty swallowing.**

**Why the study was done**

This was a pilot study. A pilot study is a small scale study done to see whether a larger study is worthwhile.

The purpose of the study was to see whether patients with head and neck cancer were interested in volunteering, figure out whether acupuncture could be done and results measured, and find out whether acupuncture helped swallowing problems and quality of life. However, any results from a pilot study are not final.

Difficulty swallowing is a common side effect of the drugs and x-ray therapy patients with head and neck cancer receive.

**Study information**

This study included:

* Study group: 42 men and women over 18 years old who had head and neck cancer that had not spread to other parts of their body and who had received drugs and x-ray therapy to treat their cancer.
* Acupuncture sessions: half of the group were scheduled to receive actual acupuncture sessions, and the other half fake acupuncture sessions; the sessions were scheduled every 2 weeks for a total of 24 weeks.

This study started in December 2008 and ended in August 2015. It was run in Massachusetts, United States. This study may finish before other studies that also study this. When they are all done, the researchers will look at the results across the studies.

**How the study worked**

Patients in the study were put into 2 groups by chance (randomized). Each patient had the same chance to be selected for either group in the study.

**Group A** had 21 patients who were planned to get 12 sessions of actual acupuncture.

**Group B** had 21 patients who were planned to get 12 sessions of fake acupuncture

Six patients left the study before it was done. Only 28 patients received all 12 sessions and 7 additional patients received at least 8 sessions of acupuncture.

Patients completed a 20 question survey to find out how they felt about their swallowing ability and other surveys to find out how they felt about their quality of life. They completed the same surveys before getting any treatments, at the very end of the treatment, and 6 months later.

**Side effects**

No patients in this study experienced serious side effects.

There may be more details in other resources listed under *Final Comments* below.

Safety evaluations were done at each acupuncture visit. The acupuncturist asked the participant whether he or she had experienced any bleeding, painful bruising at needle sites, and/or fatigue as a result of acupuncture. The answers were recorded and became part of this study.

**Summary of results**

**These results are for patients over 18 years old who have head and neck cancer and who have received drugs and x-ray treatment before** **receiving acupuncture sessions.**

Results are limited to the particular people studied here and cannot be assumed to be true for everybody. Not all participants in each part of the study had the same results.

**The study found that:**

In general, the survey showed that both groups (active acupuncture and fake acupuncture) had less difficulty swallowing. The two groups were not different.

Also, compared to fake acupuncture, actual acupuncture did not change how long patients needed a feeding tube.

**Main conclusions:**

This small study showed that acupuncture is a safe treatment for head and neck cancer patients. Some improvements in both swallowing and quality of life measurements were seen, but this schedule of acupuncture treatments did not seem to change the outcome.

In order to know whether acupuncture improved swallowing in head and neck cancer patients, further studies would need to be done, perhaps giving acupuncture treatments more often or for longer periods of time.

**Final comments**

This research may help future patients and families by helping us understand more about acupuncture treatments. Findings from this study will be used to inform future research.

This study is officially known as: Acupuncture for Dysphagia After Chemoradiation Therapy in Head and Neck Cancer Patients: A Pilot Randomized Control Trial. ClinicalTrials.gov identifier: NCT00797732.

More information may be available by looking up the official number or title.

This study was sponsored by the Dana-Farber Cancer Institute, in collaboration with the National Center for Complementary and Integrative Health (NCCIH).

You can also find more details about this study at:

* ClinicalTrials.gov: <https://clinicaltrials.gov/show/NCT00797732>
* Contemporary Clinical Trials: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3374395/>
* Medscape: <http://www.medscape.com/viewarticle/813148>

For more information about the disease/condition:

* Dysphagia (difficulty swallowing): <http://umm.edu/health/medical/altmed/condition/dysphagia>

For general information about research studies, go to [*https://www.clinicaltrials.gov/ct2/about-studies/learn*](https://www.clinicaltrials.gov/ct2/about-studies/learn)*,*

This research was important. If you have questions, please contact Zakim Center at 617-632-3322 or Zakim\_Center@dfci.harvard.edu
***Thank you again for your interest in this study.***

**Appendix 2: Study 2 Plain Language Template**

**A Pilot Study on a Mind-Body Intervention for Irritable Bowel Syndrome and Inflammatory Bowel Disease**

***Thank you for your interest in this study.***

As a clinical study participant, you belong to a large community of participants around the world. You help researchers answer important health questions and help them discover new medical treatments.

The researchers of this study think it is important for you to know the results. We hope it helps you understand and feel proud of your key role in medical research.

Here we describe the results of this study.

We completed this summary on January 4, 2017. Newer information may now exist. This summary includes only results from one single study. Other studies may find different results.

**This study explored whether a mind-body intervention affected people with irritable bowel syndrome and inflammatory bowel disease.**

**Why the study was done**

This was a pilot study. A pilot study is a small-scale study done to see whether a larger study is worthwhile.

Irritable bowel syndrome is a common disorder that affects the bowels (intestines or gut). It causes cramping, abdominal pain, bloating, gas, diarrhea and constipation. Inflammatory bowel disease is a long lasting and serious condition that involves inflammation of all or part of the digestive tract. It can lead to diarrhea, pain, tiredness, and weight loss, and to the need for surgery to treat the disease or its complications.

The purpose of this study was to see if a group mind-body intervention would be a good way to help people who have irritable bowel syndrome or inflammatory bowel disease feel better. In addition, the study also looked at whether the mind-body intervention led to improvements in mood and stress, levels of certain chemicals in the blood (markers of inflammation or swelling), or changes in how genes are turned on and off.

**Study information**

This study included:

* Study group: 48 adult patients who had irritable bowel syndrome (19 participants) or inflammatory bowel disease (29 participants) were recruited from the Massachusetts General Hospital Gastrointestinal Clinic, other Massachusetts General Hospital primary care providers, and the general public.
* Intervention: The study group received 9 weeks of a group mind-body intervention that focused on stress reduction, skills for coping with stress, and healthy behaviors. Activities such as meditation, yoga, and writing in a journal were included. Participants also received 13 follow up visits over four months.

This study started in June 2009 and ended in July 2011. It took place in Massachusetts, United States.

Four irritable bowel syndrome and five inflammatory bowel disease patients withdrew during the program after 1 to 3 sessions.

**How the study worked**

Everyone in the study participated in the group.

The group included:

* Daily relaxation methods such as meditation, breathing techniques and yoga
* Learning various mental skills and healthy lifestyle behaviors
* Teaching hopefulness and acceptance
* Teaching about how the diseases affect the GI system

Additionally, participants were asked to practice techniques they learned to elicit the relaxation response at home each day for 15-20 minutes.

Study participants completed surveys at the outset, halfway through, and at the end of the program, and then three weeks later. The surveys measured symptoms, anxiety, pain, and quality of life. Blood samples were taken at the outset and a week after the study ended.

**Side effects**

Some patients felt lightheaded or dizzy when they gave blood samples, or pain and bruising where the needle went in. There were no serious side effects or side effects directly related to the intervention.

**Summary of results**

**These results apply to patients over 18 years who have irritable bowel syndrome or inflammatory bowel disease** **and who have participated in the mind-body group.**

Results cannot be assumed to be true for everybody. Not all participants in each part of the study had the same results.

**The study found that:**

Patients with either irritable bowel syndrome or inflammatory bowel disease who participated in the mind-body intervention experienced less symptoms of anxiety and more overall quality of life. This was the case at the end of the study period and three weeks later. While there were no chemical changes in the blood, there were changes in how much some genes were turned on and off, including genes known to control inflammation.

**Main conclusions:**

This small pilot study showed that this mind-body intervention is a treatment without severe side effects for patients with irritable bowel syndrome and inflammatory bowel disease. It showed that some patients with these diseases who participated in the mind-body intervention experienced less physical symptoms and less stress and anxiety.

Larger studies are needed in the future to confirm the results of this study.

**Final comments**

This research may help future patients and families by helping us understand more about mind-body treatments for people with irritable bowel syndrome and inflammatory bowel disease and how these treatments work. Findings from this study will help to plan future research.

This study is officially known as: Effects of Relaxation Response Mind-body Intervention in Patients with IBS and IBD. ClinicalTrials.gov identifier: NCT02136745.

More information may be available by looking up the official number or title.

This study was sponsored by Massachusetts General Hospital.

You can also find more details about this study at:

* ClinicalTrials.gov: <https://clinicaltrials.gov/show/NCT02136745>
* PubMed: <http://www.ncbi.nlm.nih.gov/pubmed/25927528>
* Harvard Gazette: http://news.harvard.edu/gazette/story/2015/05/meditation-may-relieve-ibs-and-ibd/

For more information about the disease/condition:

* Irritable bowel syndrome: <http://www.mayoclinic.org/diseases-conditions/irritable-bowel-syndrome/basics/definition/con-20024578>
* Inflammatory bowel disease: <http://www.mayoclinic.org/diseases-conditions/inflammatory-bowel-disease/basics/definition/con-20034908>

For general information about research studies, go to: [*https://www.clinicaltrials.gov/ct2/about-studies/learn*](https://www.clinicaltrials.gov/ct2/about-studies/learn)

This research was important. If you have questions, please contact John W. Denninger (jdenninger@mgh.harvard.edu).

***Thanks again for your interest in this study.***

**Appendix 3: Survey (Study 2 version)**

**Survey about study results**

Check the most appropriate response.

1. With which gender do you most identify?
2. Male
3. Female
4. Prefer not to answer
5. Age range:
6. 18-30
7. 31-50
8. 51-70
9. 71 and older
10. What condition(s) do you have? Choose all that apply.
	1. Diseases of the nervous system (including anxiety, attention deficit disorder)
	2. Heart and lung diseases (including high blood pressure, asthma)
	3. Cancer
	4. Diabetes, and diseases of blood or hormones, urinary or genital system
	5. Gastrointestinal diseases (including bowel problems)
	6. Arthritis and other problems of the joints and muscles
	7. Other non-infectious diseases of long duration
	8. Injuries and accidents
	9. Other: …….
11. What kind of complementary and alternative medicine (CAM) therapy have you received? Choose all that apply.
	1. Acupuncture
	2. Ayurveda
	3. Biofeedback
	4. Chiropractic or osteopathic manipulation
	5. Chelation therapy
	6. Cranio-sacral therapy
	7. Crystals/magnets
	8. Energy Healing (e.g., therapeutic touch, reiki)
	9. Herbs or supplements (e.g., Echinacea, fish oil)
	10. Homeopathic Remedies
	11. Hypnosis
	12. Massage
	13. Meditation
	14. Modified diet (e.g., gluten free, vegan, FODMAP)
	15. Movement techniques (e.g., Alexander technique, Feldenkrais, Pilates)
	16. Moxibustion
	17. Naturopathic treatments
	18. Relaxation techniques (e.g., guided imagery, deep breathing, mind body medicine group)
	19. Traditional Healer (e.g., shaman, medicine man, curandero)
	20. Vitamins /minerals
	21. Yoga/Tai Chi/Qigong
	22. None of these
12. How would you rate your general knowledge about alternative, complementary and/or integrative medicine?
	1. Very informed
	2. Somewhat informed
	3. Not very informed
	4. Not at all informed
13. How would you rate your general knowledge of clinical trials (also called human research studies)?
14. Very informed
15. Somewhat informed
16. Not very informed
17. Not at all informed
18. Have you ever participated in (i.e., joined or enrolled in) a clinical trial?
19. Yes
20. No
21. I am not sure
22. If you answered Yes to Question 7:

What kind of clinical trial(s) were you in? (Check all that apply)

1. Medications and/or Medical Devices
2. Surgery and/or Radiation
3. Donation of blood or tissue for research
4. Complementary and alternative medicine
5. Other: …………
6. If you answered Yes to Question 7, did you read or hear anything about the results of your clinical trial?
7. Yes
8. No
9. I am not sure

If Yes, how did you learn about the results? (check all that apply)

1. Email
2. Website
3. Letter mailed to home address
4. In-person meeting
5. Phone call
6. Social media
7. Other
8. Do you think researchers *should* share the overall results of a study (that is summary results, not your individual results) with the participants?
9. Yes
10. No
11. I am not sure

 Please explain your answer:

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If YES, how do you think we should share the overall study results with participants? (please rank order; starting with “1” for your most preferred choice)

1. Email
2. Website
3. Letter mailed to home address
4. In-person meeting
5. Phone call
6. Social media
7. As long as results are shared, it doesn’t matter how

Please explain why?

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Before you answer the next questions, please review the summary of “A pilot study on a Mind-Body Intervention for Irritable Bowel Syndrome and Inflammatory Bowel Disease” and note what you find helpful and not so helpful. After you read the summary, please respond to the questions below.

1. As an example of sharing results with participants, would this summary have been helpful overall to understand the study results?
2. Yes
3. No

Please explain your answer.

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1. As an example of sharing results with participants, do you think anything in this summary was unhelpful or unclear?
2. Yes
3. No

Please explain your answer.

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