

Education and Self-efficacy of Probiotic Use in Patients with Chronic Gastrointestinal Symptoms

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INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

Abstract

Functional GI disorders are categorized as a group of chronic symptoms that are considered to have no abnormalities that can account for patient's illnesses. Included in this category are those patients with irritable bowel syndrome. Functional GI issues are an important public health concern as they are becoming increasingly more common; they can be disabling and can cause significant socioeconomic burden in regard to health care costs, productivity and disability. There is strong evidence that probiotics have the potential to reduce IBS symptoms. Unfortunately, probiotics are underutilized in the clinical setting.

The purpose of this project is to increase knowledge and self-efficacy in patients with functional GI symptoms regarding the use of probiotics for symptom management. Patients in an outpatient GI practice in Southwestern United States with chronic functional GI symptoms were shown an educational video regarding the origins and benefits of using probiotics to manage chronic symptoms. Knowledge of probiotics, self-efficacy and willingness to utilize probiotics was measured by asking participants to complete a modified Health Belief Model survey before and after viewing the video. Patient demographics were collected. There were 75 participants ($n=75$) who participated in the project with a mean age of 40.3 years ($SD=15.41$), 85% female and 15% male. Wilcoxon signed rank test were used to analyze changes in paired data with significant improvements in self-efficacy ($Z=3.93$, $p<.01$), benefits of probiotic use ($Z=4.33$, $p<.01$) and decreased barriers to probiotics use ($Z=-4.31$, $p<.01$). After participants viewed the educational video, 95% of patients indicated they would try probiotics (CI 95%, $p<.01$) versus 65% of patients who would try probiotics before viewing video. In conclusion, education regarding using probiotics to manage functional GI symptoms improved patient's self-efficacy and their willingness to use probiotics to manage their symptoms. *Keywords:* probiotics, GI disorders, diarrhea, IBS, constipation, abdominal pain, self-efficacy.

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

Education and Self-efficacy of Probiotic Use in Patients with Chronic Gastrointestinal Symptoms

Functional gastrointestinal (GI) disorders are categorized as a group of chronic symptoms that are considered to have no structural or biochemical abnormalities that can account for patient's illness. Included in this category are those patients diagnosed with irritable bowel syndrome (IBS). IBS is chronic GI disorder characterized by abdominal pain accompanied by altered bowel function, gas and bloating without the presence of organic disease (Mapel, 2013). Functional gastrointestinal symptoms typically include complaints of long-standing issues (greater than 3 months) of diarrhea, abdominal pain, constipation, gas and bloating.

Background and Significance

Functional GI issues have become an important public health concern for a number of reasons: they are becoming increasingly more common; they can be disabling and can cause significant socioeconomic burden in regard to health care costs, productivity and disability (Mapel, 2013). According to the National Institute of Health, chronic gastrointestinal symptoms account for over \$40 billion/year in health care in direct and indirect costs in the United States (U.S. Department of Health and Human Services, 2012). These costs place IBS among the 10 most expensive GI diseases in the U.S. and is one of the most common reasons for visits to gastroenterologists and primary care physician offices (Ford et al., 2014). Approximately 3600 patient are seen per year in an outpatient gastroenterology clinic located in Southwestern United States, 67% (2142) of the patients had diagnosis codes that included some combination of abdominal pain, gas, bloating, IBS and constipation and were seen at least once a month for a 6 month period for these symptoms. On average each office visit was approximately 20 minutes to 45 minutes in length with a mean average of 30 minutes/office visit. At an average collected cost of \$65.00/office visit, approximately \$390.00 was spent on each patient in a 6 month time period

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

for a total collected cost of \$1,670,760.00 in health care dollars spent on intractable GI symptoms per year at this clinic. Each office visit is allocated 15 minutes, however the mean time for an office visit for these patients was 30 minutes which affects provider time, patient satisfaction and increased staff workload. This internal data illustrates the financial burden, prevalence of the disease, and the need for further evaluation of potential effective therapies.

Purpose and Rationale

Recent interest in probiotics use has been generated from both patients and primary care providers in their use and efficacy in treating chronic gastrointestinal symptoms. Probiotics are defined by the World Health Organization (WHO) as “live microorganisms which when administered in adequate amounts confer a health benefit to the host” (World Health Organization, 2002, p.1). The term probiotic was first used in the 1960’s, however the beneficial effects of foods containing live bacteria have been recognized for centuries (Emmanuel, 2013). Biologist Elie Metchnikoff was awarded the Nobel Prize in 1908 for his pioneering research into the relationship between immunity and bacteria (Emmanuel, 2013). His seminal work led to the concept of balance between beneficial and harmful bacteria in the gut.

Probiotics, which are controlled by the U.S. Federal Drug Administration as dietary supplements, consist of yeast or bacteria and may contain a single microorganism or a combination of several species of bacteria (Hempel et al., 2012). Although the exact mechanism of action of probiotics are not known, a general consensus model proposes that lactic acid bacteria species can lower the intestinal pH which controls the growth of pathogenic bacteria, thereby reestablishing the balance of gut microbial flora (Hempel et al., 2012). In addition, other proposed mechanisms of action include immunomodulation, production of pathogenic bacterial toxins and the obstruction of pathogen adhesion to intestinal epithelium cells lining the GI tract. (Ford et al., 2014).

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

As probiotics have grown in popularity, knowledge of the implications regarding probiotic effectiveness and the need for patient education regarding their use needs to be paramount for providers. In addition, there have been conflicting media reports on probiotics which has led to increased confusion among patients as well as among health professionals as to the effectiveness of probiotics in treating GI symptoms. This inquiry has led to the clinically relevant **PICOT Question**: In adult patients seen in the outpatient setting, does the use of further education regarding probiotics increase patient's willingness and self-efficacy to use probiotics in patients with chronic GI symptoms (diarrhea, constipation, gas, bloating, IBS) ?

Search Strategy and Study Selection

A thorough literature search of multiple data bases was performed. Studies were identified through searching electronic databases and scanning reference lists of relevant articles published within the past ten years. An electronic search of the published literature was conducted using PubMed, CINAHL, and the Cochrane Central Registry of Controlled Trials for relevant studies. The principal search word terms and MESH headings used alone and in combination were: *probiotics / abdominal, probiotics / diarrhea / adult, symbiotic, probiotics / constipation, probiotics /abdominal pain, probiotics/bloating, probiotics/irritable bowel syndrome (IBS), and diarrhea/probiotics* (Appendix A).

The results of all the relevant databases were further refined with limits applied to exclude articles that were older than five years, non-English written articles and articles that included patients under the age of 18. In addition, articles that addressed in-patient populations were also excluded. Over half of these studies were dismissed due to poor study design, small sample size, insignificant results or inherent bias. The ten studies chosen for inclusion met the inclusion criteria and were relevant to all aspects of the PICOT question.

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

Evidence Synthesis

Despite the limitation of several studies included in this review, there is strong Level I and II evidence that probiotics have the potential to reduce IBS symptoms, antibiotic associated diarrhea, abdominal pain and bloating.

This evidence suggests the strongest basis for the use of probiotics has been in the treatment of diarrhea caused by antibiotics and acute diarrheal episodes in adult subjects. A systematic review of the literature by Weichselbaum (2009), revealed seven large, randomized, controlled studies of which six were shown to have a significant reduction in severity and duration of diarrheal symptoms with mixed strains of probiotic use compared to placebo (Appendix B). In addition, a number of studies reviewed by Chatterjee et al. (2013) also showed a statistically significant reduction in abdominal pain, gas, and bloating that often accompany diarrheal episodes. These findings were further supported by a systematic review of the evidence by Szajewska and Kodziej (2015) who examined 21 randomized controlled trials and found 15 studies that showed a significant reduction in antibiotic associated diarrhea with the use of probiotics over placebo. In adult patients, diarrhea was reduced from 17% to 8% (RR .043, 95% CI: 0.3-0.6) with the use of the probiotic *S.boulevardii* in various dosage amounts over placebo (Appendix B). A review of the evidence does suggest a significant reduction in antibiotic associated diarrhea duration and severity with the use of multiple probiotic strains with an adequate safety profile.

Parkes, Sanderson and Whelan (2010), reviewed 17 studies with adult patients diagnosed with irritable bowel syndrome and found a significant decrease in diarrhea, abdominal pain, gas and bloating symptoms with probiotic use in half the studies reviewed, but no change in constipation symptoms (Appendix B). A meta-analysis by Dimidi, Christodoulides, Konstantinos, Scott and Whelan (2014), evaluated the results of 14 randomized, placebo-controlled trials in adult

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

patients to determine the efficacy of probiotics for IBS symptoms (Appendix B). Overall probiotics significantly reduced constipation measured by whole gut transit time by 12 hours (95% CI: -22.3, -2.5 hour, $p < .01$) and increased stool frequency by 1.3 bowel movements per week (95% CI: 0.07, 1.9 bowel movement/week, $p < .01$) compared to placebo in five studies (Appendix B). Although multiple strains of probiotics were used in the included studies, the probiotic strain *Bifidobacterium lactis* was used frequently and had the most significant effect on IBS symptoms.

This data was further supported by a randomized, placebo controlled trial conducted by Waller et al. (2011), that showed a statistically significant 33% decrease in constipation, 27% reduction in abdominal pain and 32% reduction in bloating over 14 day study period with the use of *Bifidobacterium lactis* over placebo in IBS patients (Appendix B). In addition, two randomized, placebo controlled trials conducted by Rogha, Esfahani and Zargarzadeh (2014) and Pineton de Chambrun et al. (2015) both showed a significant decrease in abdominal pain, bloating and diarrhea frequency with the use of probiotic over placebo, but failed to show a difference in constipation (Appendix B). Although several studies by Esken et al. (2015) showed a significant change in bowel movements with a decrease in constipation, this data remains unsupported by larger, randomized study results (Appendix B). Ford et al. (2014) reviewed 64 randomized controlled trials and found a majority that showed significant reduction in IBS symptoms (Appendix B). In a majority of the IBS studies reviewed there appears to be a significant reduction in abdominal pain, gas, bloating and diarrhea with the use of probiotics, but little effect on constipation symptoms.

Summary Recommendations

The pathogenesis of functional GI disorders and IBS remains unclear and at least in part, appears multifactorial with numerous factors contributing to symptom severity. The possibility that

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

gut microbiota may have a role in IBS symptom relief is supported by sufficient Level I evidence that a number of probiotic strains are effective in reducing antibiotic associated diarrhea severity and duration in addition to abdominal pain, gas, and bloating associated with IBS (Appendix B). In addition, due to the lack of current treatment options for IBS patients and the adequate probiotic safety profile, their use could be a viable option for many patients. Overall, the data illustrates the safety and effectiveness of probiotics use to reduce IBS symptoms: including abdominal pain, gas, bloating and diarrhea.

Theoretical Framework

Overall the research suggests probiotics may have a benefit in practice in specific patient populations. This recommendation is based on Stetler's Model of Research utilization evidenced based practice model within the framework of the Health Belief Model (HBM) theoretical paradigm . This model allows for the unique patient /provider relationship based on evaluation of patient behavior, motivation and learning in an environment of caring and trust and incorporates phases of research utilization based on a foundation of critical thinking (White, K.M., Dudley-Brown, S. & Terhaar, M., 2016) .

The Stetler model is composed of five phases of research utilization: preparation, validation, comparison, implementation and evaluation (Stetler, C.B., et al., 1998). The evidence from internal data obtained from the outpatient GI clinic supports the current literature with regards to financial burden, prevalence and the need for further evaluation of potential effective therapies in functional GI disorders. The clinical expertise was further added to the decision making process in determining patient symptomology, diagnosis and available treatment modalities. This led to a comprehensive review of the available evidence which supports the use of probiotics as a valid treatment option for patients.

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

The Health Belief Model (HBM) allows for successful change based on an evaluation of patient behavior, motivation and learning in an environment of caring and trust and incorporates phases of behavior change based on a foundation of critical thinking and self-efficacy (Rosenstock, 1966). The theory consists of four main constructs: susceptibility, seriousness of health condition, perceived benefits, and barriers (Rosenstock, 1966). Underlying the HBM theory is the concept of knowledge, which plays a key role in health motivation and self-efficacy.

Guided by Knowles Adult Learning theory, providing education that is patient centered, goal driven and involves a direct impact on their health can influence health outcomes (Knowles, G.J., 1998). According to Knowles' Adult Learning Theory, adult learning provides the underpinnings of a patient's willingness to change behaviors and utilize probiotics. Adult learning provides the underpinnings of a patient's willingness to change behaviors and utilize probiotics.

Methods

The purpose of the project is to provide education to patients with chronic GI symptoms regarding probiotic use to manage symptoms and to evaluate if this education changes the patient's willingness and self-efficacy to use probiotics as a means to manage their symptoms.

Participants/Measures

Participants were adult patients with chronic functional GI symptoms seen at an outpatient GI clinic in Southwestern United States. Eligible participants included adult English speaking patients over the age of 18 with chronic GI symptoms (diarrhea, constipation, gas, bloating, IBS) seen in the outpatient setting. Arizona State University Institutional Review Board approval was obtained for study protocols prior to the start of project implementation and exempt status was granted. Participants were assured of strict confidentiality as all study material was anonymous and de-identified and kept in a locked office. Study participants were informed of all project

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

requirements and verbal consent was obtained from each patient prior to obtaining any project data. Collaboration with healthcare team which included physician, medical assistant and office staff regarding project evaluation, implementation and budget was effectively communicated by weekly meetings with the use of transformational leadership constructs.

Participants were shown an educational video regarding the origins and benefits of using probiotics to manage chronic GI symptoms. Knowledge of probiotics, self-efficacy and willingness to utilize probiotics was measured by asking participants to complete a modified Health Belief Model survey before and after viewing the video.

The modified HBM survey included a total of 22 questions within six domains: perceived susceptibility, perceived seriousness, perceived benefits, perceived barriers, self-efficacy and knowledge and one question regarding willingness to use probiotics (Rosenstock, 1966). The scale utilized a five point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). These items were chosen because they represent a wide range of contexts in which perceived self-efficacy has been measured reliably. The questionnaire was patterned after a valid prior survey with a reliability coefficient of .89 for the prior survey (Lee, Hwang, Hawkins, & Pingree, 2008). However, there is no a current survey that has been tested for validity and reliability that specifically addresses probiotic use and increased education. Therefore, survey language, content and construct validity were reviewed by Arizona State University professors. Demographic data including age and sex were also obtained.

Statistical analysis/Results

The Statistical Package for the Social sciences SPSS version 24.0 for Windows was used for analysis. Mean scale scores for the pre- and post-administration of each scale were evaluated for significant differences using the non-parametric Wilcoxon signed-rank test for hypothesis

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

testing of repeated measurements of a single sample. Non-parametric testing was chosen as it makes fewer assumptions about the distribution of responses, as the data was not a normal distribution. The sample included 64 females (86%) and 11 males (15%) that ranged in age from 18 to 78 ($M=40.3$, $SD=15.41$). The results were significant with 65% of patients indicating they would try probiotics before educational video while 96% would try probiotics post video (CI 95%, $p<.01$), as shown in Table 1. Significant differences were also found in the results regarding improved self-efficacy, improved benefits, decreased barriers to probiotics use, as shown in Table 2. The mean scale scores for all questions regarding self-efficacy were significantly higher post-video compared to pre-video responses. The highest statistically significant improvement was found in the self-efficacy survey question: "I have been able to meet the goals I set for myself to improve my health" ($Z=5.622$, $p<.01$). The mean scale scores for all questions regarding barriers to probiotic use were significantly reduced post-video compared to pre-video responses. The highest statistically significant decreased barrier found in the survey question was "Probiotics cost too much to use." ($Z=4.131$, $p<.01$). The mean scale scores for all questions regarding benefits of probiotic use were also significantly higher post video compared to pre video. The highest significant improvement was found in the benefit survey question "I feel the benefits associated with probiotics outweigh the risks" ($Z=5.713$, $p<.01$). Categories concerning susceptibility and seriousness overall produced few significant results, as shown in Table 2. Baseline knowledge of probiotics were assessed using three true/false questions that showed significant improvement by binomial testing in knowledge of probiotics after viewing of the video in correctly answering "Are probiotics good for you?" (91% pre-video to 100% post-video, CI 95%, $p<.01$) and "Do probiotics improve your immune system?" (91% pre-video to 100% post-video, CI 95%, $p<.01$) as shown in

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

Table 3. The question “Are you born with probiotics?” showed no significant improvement (CI 95%, *p*.49).

Discussion

The evidence supports the use of probiotics in treating functional GI symptoms and suggests increased use of probiotics in practice would be beneficial for patient outcomes. The Health Belief Model hypothesizes that patients are more likely to change a behavior if they have adequate knowledge, recognize the benefits and risks associated with treatment and strong self-efficacy (Rosenstock, 1966). This project has demonstrated that education of probiotics does significantly increase a patient’s self-efficacy regarding management of their symptoms, their perception of benefits of probiotics and decreases their barriers to using probiotics and increases patients’ willingness to use probiotics in the future.

Limitations of this evaluation included the ability to draw conclusions about the role that education itself played in the results by the fact that we did not have a comparison cohort of patients against which to compare survey results. In addition, small cohort size limited generalizability. While the project did demonstrate an increase in willingness to try probiotics, we cannot conclude that patients really did increase their utilization of probiotics, nor can we determine the effectiveness of the probiotics in management of these patients’ symptoms.

The impact of the project influenced patients, provider practice and potential system effects. Patients gained increased education and improved self-efficacy and their willingness to use probiotics. For providers and the practice, increased education will be provided to patients at each office visit, and in the future further educational videos are being considered for other disease processes such as Crohn’s disease and ulcerative colitis. Health system effects include potential decreased healthcare costs and loss of productivity associated with functional GI disorders with the

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

increased use of probiotics. The project will be sustained in the future with the continued use of the educational video and is currently being translated for Spanish speaking patients.

Conclusion

The use of probiotics in clinical practice has the potential to reduce socioeconomic burden in regard to health care costs, productivity, and disability associated with functional GI disorders. Most importantly, with few treatment options available for patients suffering from IBS and functional GI disorders, the use of probiotics may alleviate patient suffering, pain, and disability and improve quality of life. The evidence, which supports current literature, suggests the use of educations increases patients self-efficacy and their willingness to use probiotics in the future. Increased education may be an effective method of increasing the number of patients who will use probiotics in the clinical setting, therefore improving functional GI symptoms, decreasing healthcare costs and loss of productivity. Based on these results, future studies could be considered to evaluate if patients actually started taking probiotics after increased education and whether patients experience a reduction in their symptoms after starting probiotics.

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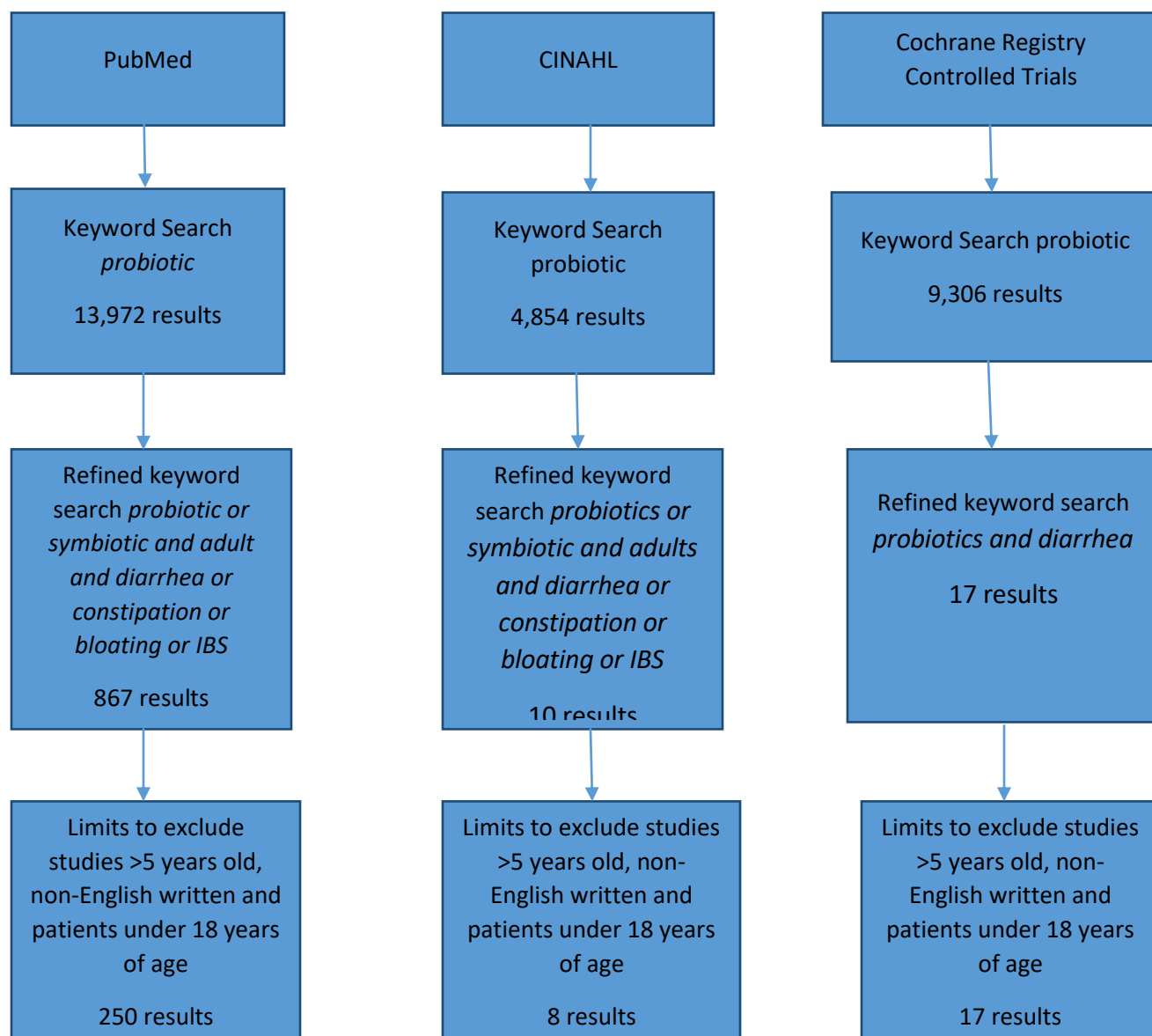
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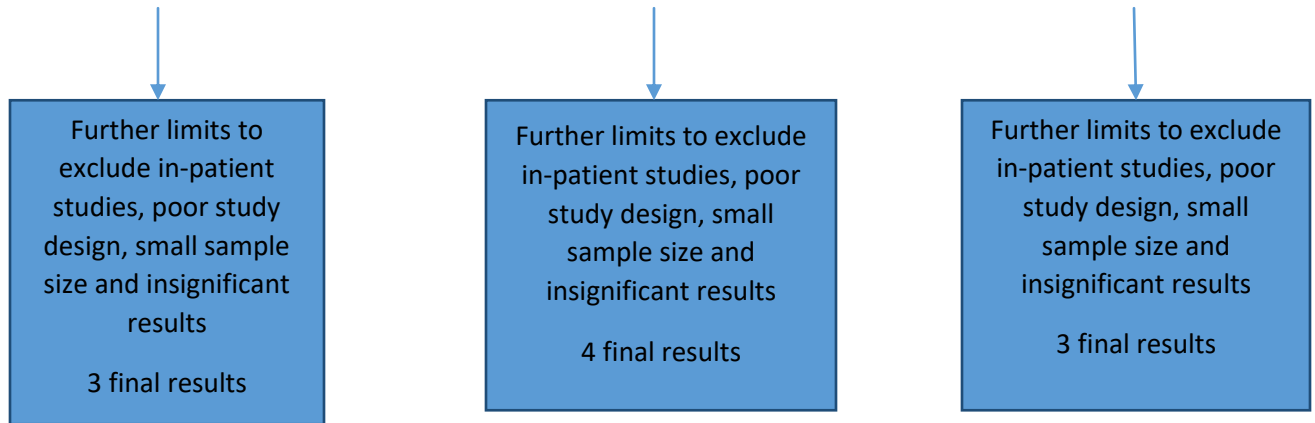
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Appendix A Database Search strategy Results Flow Chart



INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE



Running Head: INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

Appendix B Synthesis Table Summary of Evidence of Probiotic Use in Functional GI Disorders

Author Date	Type of Study	Abdominal pain	Sample Size	Constipation	Diarrhea	Gas/Bloating	IBS symptoms
Waller et al. (2011)	RCT	↓√	100	↓√		↓√	
Chatterjee et al. (2013)	RCT		396		↓√		
Rhoga et al. (2014)	RCT	↓√	85		↓√	↓√	↓√
Pineton de Chambrun et al. (2015)	RCT	↓√	179	↔√	↓√	↓√	↓√
Dimidi et al. (2014)	Meta-Analysis	↓√	14 Studies	↓√			
Eskesen (2015)	RCT	↓√	179	↓√		↓√	
Weischelbaum (2009)	Meta-Analysis	↓√	164	↔√	↓√	↓√	↓√
Parkes et al. (2010)a	Meta-Analysis		14 studies	↓√		↓√	↓√
Ford et al. (2014)	SR	↓√	64 RCT (6022 patients)			↓√	↓√
Szajewska et al. (2015)	SR		21 RCT (4078 patients)		↓√	↓√	↓√

Key: ↓Significant change in decrease of symptoms, ↔ No significant change in symptoms, √ Outcomes measured, RCT -Randomized Controlled Trial, SR-Systematic Review

Table 1 Patient willingness to try probiotics pre/post video

		Frequency	Percentage	2-tailed Significance
Would try probiotics pre-video	No	26	35	$p=.01$
	Yes	49	65	
	Total	75	100	
Would try probiotics post-video	No	3	4	$p=<.01$
	Yes	72	96	
	Total	75	100	

Note: CI(Confidence Interval 95%), significance $p<.05$

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

Table 2 Survey questions pre/post video Wilcoxon signed-rank tests

Survey Questions	Categories	Change in results	Z-score Mean difference	2-tailed significance
Probiotics cost too much to use	Barriers to probiotic use	↓√	-4.131	$p < .01$
I do not know enough about probiotics to take them	Barriers to probiotic use	↑√	3.416	$p < .01$
There are too many risks with taking probiotics	Barriers to probiotic use	↓√	-3.575	$p < .01$
Taking probiotics is inconvenient for me	Barriers to probiotic use	↓√	-2.491	$p < .01$
I am confident I can have a positive effect on my health	Self-efficacy	↑√	3.934	$p < .01$
I have some definite goals to improve my health	Self-efficacy	↑√	4.732	$p < .01$
I have been able to meet the goals I set for myself to improve my health	Self-efficacy	↑√	5.622	$p < .01$
I am actively working to improve my health	Self-efficacy	↑√	4.869	$p < .01$
I feel that I am in control of how and what I learn about my health	Self-efficacy	↑√	4.337	$p < .01$
I feel I know a lot about probiotics and how they work	Self-efficacy	↑√	5.990	$p < .01$
Having chronic GI symptoms is a reason for taking probiotics	Benefits	↑√	4.828	$p < .01$
Taking probiotics will decrease my GI symptoms	Benefits	↑√	4.942	$p < .01$
I would consider taking probiotics	Benefits	↑√	4.660	$p < .01$
I feel the benefits associated with probiotics outweigh the risks	Benefits	↑√	5.713	$p < .01$
My GI symptoms disrupt me daily life	Seriousness	↑√	3.854	$p < .01$
My GI health is important to my well being	Seriousness	↔	-3.954	$p .69$
I feel my GI symptoms are getting worse	Seriousness	↔	1.391	$p .16$
I feel my GI symptoms will get worse in the future	Susceptibility	↑√	3.204	$p < .01$
I worry a lot about my future GI health	Susceptibility	↔	.4290	$p .67$
I am aware of the possible benefits of probiotics in managing my GI symptoms	Susceptibility	↑√	3.991	$p < .01$

Note: ↓√ Significant change in decrease of patient responses, ↔ No significant change in responses, ↑√ Significant improvement of patient responses, CI(Confidence Interval 95%), significance $p < .05$

INCREASED EDUCATION AND SELF-EFFICACY IN PROBIOTIC USE

Table 3 Education of probiotic pre/post video Binomial Testing

Education Survey Binomial Test						
Survey Question	Answer	N	Percentage	Test Prop.	Exact Sig. (2-tailed)	
Probiotics are good for you Prevideo	True	68	.91	.50	<i>p</i> < .01	
	False	7	.09			
	Total	75	1.00			
Probiotics are good for you Postvideo	Group 1 True	75	1.00	.50	<i>p</i> < .01	
	Total	75	1.00			
Probiotics Improve your immune system Prevideo	Group 1 True	68	.91	.50	<i>p</i> < .01	
	Group 2 False	7	.09			
	Total	75	1.00			
Probiotics Improve your immune system Postvideo	Group 1 True	74	.99	.50	<i>p</i> < .01	
	Group 2 False	1	.01			
	Total	75	1.00			
You are born with probiotics Prevideo	Group 1 True	41	.55	.50	<i>p</i> .49	
	Group 2 False	34	.45			
	Total	75	1.00			
You are born with probiotics Postvideo	Group 1 True	70	.93	.50	<i>p</i> < .01.	
	Group 2 False	5	.07			
	Total	75	1.00			

Note: CI(Confidence Interval 95%), significance *p* < .05