BENEFITS OF PROBIOTICS - A QUICK GUIDE ON HUMAN CLINICAL STUDY LITERATURE (2000-2018)

Dr. Bobban Subhadra

HUMAN CLINICAL STUDIES: EFEECT OF PROBIOTICS ON DIABETES & METABOLIC SYNDROME

THE EFFECTS OF PROBIOTIC SUPPLEMENTATION ON METABOLIC STATUS IN TYPE 2 DIABETIC PATIENTS WITH CORONARY HEART DISEASE.

Diabetol Metab Syndr. 2018 Jun 19;10:51. doi: 10.1186/s13098-018-0353-2. eCollection 2018.

Raygan F et al

Abstract

BACKGROUND:

This study was conducted to evaluate the effects of probiotic supplementation on metabolic profiles in diabetic patients with coronary heart disease (CHD).

METHODS:

This randomized, double-blind, placebo-controlled trial was performed among 60 diabetic patients with CHD, aged 40-85 years at a cardiology clinic in Kashan, Iran, from October 2017 through January 2018. Patients were randomly divided into two groups to take either probiotic supplements (n = 30) or placebo (n = 30) for 12 weeks. Fasting blood samples were taken at the beginning of the study and after the 12-week intervention to determine related markers.

RESULTS:

After 12-week intervention, probiotic supplementation significantly decreased fasting plasma glucose (β - 20.02 mg/dL; 95% CI - 33.86, - 6.17; *P* = 0.005), insulin (β - 2.09 μIU/mL; 95% CI - 3.77, - 0.41; *P* = 0.01), insulin resistance (β - 0.50; 95% CI - 0.96, - 0.03; P = 0.03) and total-/HDL-cholesterol ratio (β - 0.27; 95% CI - 0.52, - 0.03; P = 0.02), and significantly increased insulin sensitivity (β 0.008; 95% CI 0.001, 0.01; P = 0.02) and HDL-cholesterol levels (β 2.52 mg/dL; 95% CI 0.04, 5.00; P = 0.04) compared with the placebo. Moreover, probiotic supplementation led to a significant reduction in serum high sensitivity C-reactive protein (β - 0.88 mg/L; 95% CI - 1.39, - 0.38; *P* = 0.001), and a significant elevation in total antioxidant capacity (β 108.44 mmol/L; 95% CI 47.61, 169.27; *P* = 0.001) and total glutathione levels (β 45.15 μmol/L; 95% CI 5.82, 84.47; *P* = 0.02) compared with the placebo. Probiotic supplementation did not affect other metabolic profiles.

CONCLUSIONS:

Overall, we found that probiotic supplementation for 12 weeks had beneficial effects on glycemic control, HDL-cholesterol, total-/HDL-cholesterol ratio, biomarkers of inflammation and oxidative stress in diabetic patients with CHD.*Trial registration* Clinical trial registration number http://www.irct.ir: IRCT2017082733941N5.

EFFECT OF MULTISPECIES PROBIOTIC SUPPLEMENTS ON METABOLIC PROFILES, HS-CRP, AND OXIDATIVE STRESS IN PATIENTS WITH TYPE 2 DIABETES.

Ann Nutr Metab. 2013;63(1-2):1-9. doi: 10.1159/000349922. Epub 2013 Jul 5.

Asemi Z et al

Abstract

BACKGROUND:

We are aware of no study that has indicated the effects of daily consumption of multispecies probiotic supplements on metabolic profiles, high-sensitivity C-reactive protein (hs-CRP), and oxidative stress in diabetic patients.

OBJECTIVE:

This study was designed to determine the effects of multispecies probiotic supplements on metabolic profiles, hs-CRP, and oxidative stress in diabetic patients.

METHODS:

This randomized double-blind placebo-controlled clinical trial was performed on 54 diabetic patients aged 35-70 years. Subjects were randomly assigned to take either a multispecies probiotic supplement (n = 27) or placebo (n = 27) for 8 weeks. The multispecies probiotic supplement consisted of 7 viable and freeze-dried strains: Lactobacillus acidophilus (2 × 10(9) CFU), L. casei (7 × 10(9) CFU), L. rhamnosus (1.5 × 10(9) CFU), L. bulgaricus (2 × 10(8) CFU), Bifidobacterium breve (2 × 10(10) CFU), B. longum (7 × 10(9) CFU), Streptococcus thermophilus (1.5 × 10(9) CFU), and 100 mg fructo-oligosaccharide. Fasting blood samples were taken at baseline and after intervention to measure metabolic profiles, hs-CRP, and biomarkers of oxidative stress including plasma total antioxidant capacity and total glutathione (GSH).

RESULTS:

Between-group comparisons of fasting plasma glucose (FPG) revealed that consumption of probiotic supplements prevented a rise in FPG (+28.8 ± 8.5 for placebo vs. +1.6 ± 6 mg/dl for probiotic group, p = 0.01). Although a significant within-group increase in serum insulin and low-density lipoprotein cholesterol levels was found in both the probiotic group and the placebo group, the changes were similar between the two groups. We observed a significant increase in HOMA-IR (homeostasis model of assessment-insulin resistance) in both the probiotic group (p = 0.02) and the placebo group (p = 0.001); however, the increase in the placebo group was significantly higher than that in the probiotic group (+2.38 vs. +0.78, p = 0.03). Mean changes in serum hs-CRP were significantly different between the two groups (-777.57 for the probiotic group vs. +878.72 ng/ml for the placebo group, p = 0.02). Probiotic supplementation led to a significant increase in plasma GSH levels compared to placebo (240.63 vs. -33.46 μmol/l, p = 0.03).

CONCLUSION:

In conclusion, multispecies probiotic supplementation, compared with placebo, for 8 weeks in diabetic patients prevented a rise in FPG and resulted in a decrease in serum hs-CRP and an increase in plasma total GSH.

EFFECTS OF SYNBIOTIC FOOD CONSUMPTION ON METABOLIC STATUS OF DIABETIC PATIENTS: A DOUBLE-BLIND RANDOMIZED CROSS-OVER CONTROLLED CLINICAL TRIAL.

Clin Nutr. 2014 Apr;33(2):198-203. doi: 10.1016/j.clnu.2013.05.015. Epub 2013 Jun 7.

Asemi Z et al

Abstract

BACKGROUND & AIMS:

We are aware of no study indicating the effects of synbiotic food consumption on metabolic profiles, inflammation and oxidative stress among diabetic patients. The aim of the current study was to investigate the effects of synbiotic food consumption on metabolic profiles, hs-CRP and biomarkers of oxidative stress in diabetic patients.

METHODS:

This randomized double-blinded cross-over controlled clinical trial was performed among 62 diabetic patients aged 35-70 y. After a 2-wk run-in period, subjects were randomly assigned to consume either a synbiotic (n = 62) or control food (n = 62) for 6 weeks. A 3-week washout period was applied following which subjects were crossed over to the alternate treatment arm for an additional 6 weeks. The synbiotic food consisted of a probiotic viable and heat-resistant Lactobacillus sporogenes (1 × 10(7) CFU), 0.04 g inulin (HPX) as prebiotic with 0.38 g isomalt, 0.36 g sorbitol and 0.05 g stevia as sweetener per 1 g. Control food (the same substance without probiotic bacteria and prebiotic inulin) was packed in identical 9-gram packages. Patients were asked to consume the synbiotic and control foods three times a day. Fasting blood samples were taken at baseline and after a 6-wk intervention to measure metabolic profiles, hs-CRP and biomarkers of oxidative stress.

RESULTS:

Consumption of a synbiotic food, compared to the control, resulted in a significant decrease in serum insulin levels (changes from baseline: -1.75 ± 0.60 vs. +0.95 ± 1.09 μIU/mL, P = 0.03). Although we failed to find a significant effect of synbiotic food consumption on total- and LDL-cholesterol levels and HOMA-IR, the effects on FPG (22.3 vs. 4.2 mg/dL, P = 0.09), serum triglycerides (45.9 vs. 20.6 mg/dL, P = 0.08) and HDL-cholesterol levels (3.1 vs. -2 mg/dL, P = 0.06) tended to be significant. A significant reduction in serum hs-CRP levels (-1057.86 ± 283.74 vs. 95.40 ± 385.38 ng/mL, P = 0.01) was found following the consumption of synbiotic food compared with the control group. Supplementation with the synbiotic food led to a significant increase in plasma total GSH (319.98 vs. 19.73 μmol/L, P < 0.001) and serum uric acid levels (+0.7 vs. -0.1 mg/dL, P = 0.04) compared to the control food. No significant effect of the synbiotic food was observed on plasma TAC levels.

CONCLUSIONS:

In conclusion, consumption of a synbiotic food for 6 weeks among diabetic patients had significant effects on serum insulin, hs-CRP, uric acid and plasma total GSH levels.

CLINICAL AND METABOLIC RESPONSE TO PROBIOTIC ADMINISTRATION IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL.

Nutrition. 2016 Mar;32(3):315-20. doi: 10.1016/j.nut.2015.09.003. Epub 2015 Sep 28.

Akkasheh G **et al**

Abstract

OBJECTIVE:

We are aware of no study examining the effects of probiotic supplementation on symptoms of depression, metabolic profiles, serum high-sensitivity C-reactive protein (hs-CRP), and biomarkers of oxidative stress in patients with major depressive disorder (MDD). The present study was designed to determine the effects of probiotic intake on symptoms of depression and metabolic status in patients with MDD.

METHODS:

This randomized, double-blind, placebo-controlled clinical trial included 40 patients with a diagnosis of MDD based on DSM-IV criteria whose age ranged between 20 and 55 y. Patients were randomly allocated into two groups to receive either probiotic supplements (n = 20) or placebo (n = 20) for 8 wk. Probiotic capsule consisted of three viable and freeze-dried strains: Lactobacillus acidophilus (2 × 10(9) CFU/g), Lactobacillus casei (2 × 10(9) CFU/g), and Bifidobacterium bifidum (2 × 10(9) CFU/g). Fasting blood samples were taken at the beginning and end of the trial to quantify the relevant variables. All participants provided three dietary records (two weekdays and one weekend) and three physical activity records during the intervention.

RESULTS:

Dietary intake of study participants was not significantly different between the two groups. After 8 wk of intervention, patients who received probiotic supplements had significantly decreased Beck Depression Inventory total scores (-5.7 ± 6.4 vs. -1.5 ± 4.8, P = 0.001) compared with the placebo. In addition, significant decreases in serum insulin levels (-2.3 ± 4.1 vs. 2.6 ± 9.3 μIU/mL, P = 0.03), homeostasis model assessment of insulin resistance (-0.6 ± 1.2 vs. 0.6 ± 2.1, P = 0.03), and serum hs-CRP concentrations (-1138.7 ± 2274.9 vs. 188.4 ± 1455.5 ng/mL, P = 0.03) were observed after the probiotic supplementation compared with the placebo. Additionally, taking probiotics resulted in a significant rise in plasma total glutathione levels (1.8 ± 83.1 vs. -106.8 ± 190.7 μmol/L, P = 0.02) compared with the placebo. We did not find any significant change in fasting plasma glucose, homeostatic model assessment of beta cell function, quantitative insulin sensitivity check index, lipid profiles, and total antioxidant capacity levels.

CONCLUSIONS:

Probiotic administration in patients with MDD for 8 wk had beneficial effects on Beck Depression Inventory, insulin, homeostasis model assessment of insulin resistance, hs-CRP concentrations, and glutathione concentrations, but did not influence fasting plasma glucose, homeostatic model assessment of beta cell function, quantitative insulin sensitivity check index, lipid profiles, and total antioxidant capacity levels.

EFFECTS OF PROBIOTIC SUPPLEMENTATION ON METABOLIC STATUS IN PREGNANT WOMEN: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL.

Arch Iran Med. 2016 Oct;19(10):687-682.

Jamilian M et al

Abstract

BACKGROUND:

Limited data is available on the effects of multispecies probiotic supplementation on metabolic status in pregnant women in the first half of pregnancy. The current study was carried out to determine the effects of multispecies probiotic capsule supplementation on metabolic status among pregnant women in the first half of pregnancy.

METHODS:

A randomized clinical trial was conducted among 60 pregnant women aged 18-37 years. The participants were randomly divided into two groups: group A (n = 30) received multispecies probiotic supplements containing three probiotic bacteria spices Lactobacillus acidophilus, Lactobacillus casei, Bifidobacterium bifidum (2 × 109 CFU/g each) and group B (n = 30) received placebo from 9 weeks of gestation for a duration of 12 weeks. Fasting blood samples were taken at the beginning of the study and after 12 weeks of intervention to determine metabolic profiles, inflammatory cytokines and biomarkers of oxidative stress.

RESULTS:

After 12 weeks of intervention, compared to the placebo group, the pregnant women who consumed probiotic capsule had significantly decreased serum insulin concentrations (-1.5 ± 4.8 vs. +1.3 ± 5.2 μIU/mL, P = 0.03), the homeostasis model of assessment-estimated insulin resistance (HOMA-IR) (-0.3 ± 0.9 vs. +0.3 ± 1.1, P = 0.04), the homeostasis model of assessment-estimated b cell function (HOMA-B) (-7.2 ± 23.1 vs. +5.3 ± 22.6, P = 0.03) and increased quantitative insulin sensitivity check index (QUICKI) (+0.01 ± 0.05 vs. -0.01 ± 0.02, P = 0.03). In addition, changes in serum triglycerides levels (-14.7 ± 46.5 vs. +37.3 ± 74.2 mg/dL, P = 0.002), high-sensitivity C-reactive protein (hs-CRP) (-1.0 ± 2.6 vs. +1.7 ± 4.3 mg/L, P = 0.004), plasma nitric oxide (NO) (+6.8 ± 9.3 vs. -4.7 ± 7.4 μmol/L, P < 0.001), total antioxidant capacity (TAC) (+171.9 ± 187.6 vs. -51.9 ± 208.8 mmol/L, P < 0.001) and glutathione (GSH) concentrations (+34.3 ± 71.6 vs. -36.9 ± 108.3 μmol/L, P = 0.004) in supplemented women were significantly different from those of the placebo group. However, after controlling for baseline levels, age and BMI at the study baseline, the changes in plasma GSH were not significantly different between the groups.

CONCLUSION:

Overall, probiotic supplementation for 12 weeks among pregnant women in the first half of pregnancy had beneficial effects on markers of insulin metabolism, triglycerides, biomarkers of inflammation and oxidative stress.

EFFECT OF PROBIOTICS ON METABOLIC OUTCOMES IN PREGNANT WOMEN WITH GESTATIONAL DIABETES: A SYSTEMATIC REVIEW AND META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS.

Nutrients. 2017 May 5;9(5). pii: E461. doi: 10.3390/nu9050461.

Taylor BL et al

Abstract

The metabolic effects of probiotic administration in women with gestational diabetes mellitus (GDM) is unknown. The objective of this review was to investigate the effect of probiotics on fasting plasma glucose (FPG), insulin resistance (HOMA-IR) and LDL-cholesterol levels in pregnant women diagnosed with GDM. Seven electronic databases were searched for RCTs published in English between 2001 and 2017 investigating the metabolic effects of a 6-8 week dietary probiotic intervention in pregnant women following diagnosis with GDM. Eligible studies were assessed for risk of bias and subjected to qualitative and quantitative synthesis using a random effects model meta-analyses. Four high quality RCTs involving 288 participants were included in the review. Probiotic supplementation was not effective in decreasing FBG (Mean Difference = -0.13; 95% CI -0.32, 0.06, p = 0.18) or LDL-cholesterol (-0.16; 95% CI -0.45, 0.13, p = 0.67) in women with GDM. However, a significant reduction in HOMA-IR was observed following probiotic supplementation (-0.69; 95% CI -1.24, -0.14, p = 0.01). There were no significant differences in gestational weight gain, delivery method or neonatal outcomes between experimental and control groups, and no adverse effects of the probiotics were reported. Probiotic supplementation for 6-8 weeks resulted in a significant reduction in insulin resistance in pregnant women diagnosed with GDM. The use of probiotic supplementation is promising as a potential therapy to assist in the metabolic management of GDM. Further high quality studies of longer duration are required to determine the safety, optimal dose and ideal bacterial composition of probiotics before their routine use can be recommended in this patient group.

EFFECTS OF PROBIOTIC SUPPLEMENTATION ON GLYCAEMIC CONTROL AND LIPID PROFILES IN GESTATIONAL DIABETES: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL.

Diabetes Metab. 2016 Sep;42(4):234-41. doi: 10.1016/j.diabet.2016.04.009. Epub 2016 May 18.

Karamali M et al

Abstract

BACKGROUND:

To our knowledge, data on the effects of probiotic supplementation on glycaemic control and lipid concentrations in patients with gestational diabetes mellitus (GDM) are scarce.

AIM:

The aim of the present study was to determine the effects of probiotic supplementation on glycaemic control and lipid profiles in GDM patients.

METHODS:

Sixty pregnant women with GDM, primigravida and aged 18-40years, were divided into two groups to receive either probiotic capsules (n=30) or a matching placebo (n=30) in this randomized double-blind, placebo-controlled trial. The patients in the probiotic group took a daily capsule that contained three viable freeze-dried strains: Lactobacillus acidophilus (2×10(9)CFU/g), L. casei (2×10(9)CFU/g) and Bifidobacterium bifidum (2×10(9)CFU/g) for 6weeks. The placebo group took capsules filled with cellulose for the same time period. Fasting blood samples were taken at the beginning and end of the study to quantify the relevant markers.

RESULTS:

After 6weeks of intervention, probiotic supplementation vs a placebo resulted in significant decreases in fasting plasma glucose (-9.2±9.2mg/dL vs +1.1±12.2mg/dL, P<0.001), serum insulin levels (-0.8±3.1μIU/mL vs +4.5±10.6μIU/mL, P=0.01), homoeostasis model assessment (HOMA) for insulin resistance (-0.4±0.9 vs +1.1±2.5, P=0.003) and HOMA for β-cell function (+1.1±9.8 vs +18.0±42.5, P=0.03), and a significant increase in the quantitative insulin sensitivity check index (+0.007±0.01 vs -0.01±0.02, P=0.007). In addition, significant decreases in serum triglycerides (-1.6±59.4mg/dL vs +27.1±37.9mg/dL, P=0.03) and VLDL cholesterol concentrations (-0.3±11.9mg/dL vs +5.4±7.6mg/dL, P=0.03) were seen following supplementation with the probiotics compared with the placebo. However, no significant changes in other lipid profiles were seen with the intervention.

CONCLUSION:

Overall, the results of our study have demonstrated that taking probiotic supplements for 6weeks in patients with GDM had beneficial effects on glycaemic control, triglycerides and VLDL cholesterol concentrations, although there was no effect on other lipid profiles.

THE EFFECTS OF SYNBIOTIC SUPPLEMENTATION ON MARKERS OF INSULIN METABOLISM AND LIPID PROFILES IN GESTATIONAL DIABETES: A RANDOMISED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL.

Br J Nutr. 2016 Oct;116(8):1394-1401. Epub 2016 Sep 29.
Ahmadi S et al

Abstract

To the best of our knowledge, data on the effects of synbiotic supplementation on markers of insulin metabolism and lipid concentrations in patients with gestational diabetes mellitus (GDM) are scarce. The aim of the current study was to determine the effects of synbiotic supplementation on markers of insulin metabolism and lipid profiles in GDM patients. In total, seventy patients with GDM aged 18-40 years were assigned to two groups - the synbiotic group (n 35) and the placebo group (n 35) - in this randomised, double-blind, placebo-controlled trial. Patients in the synbiotic group received a daily capsule that contained three viable and freeze-dried strains: Lactobacillus acidophilus, Lactobacillus casei and Bifidobacterium bifidum (2×109 colony-forming units/g each) plus 800 mg inulin for 6 weeks. Fasting blood samples were collected at the beginning and week 6 to quantify related markers. After 6 weeks of intervention, compared with the placebo, synbiotic supplementation led to a significant decrease in serum insulin levels (-1·5 (sd 5·9) v. +4·8 (sd 11·5) μIU/ml, P=0·005), homoeostatic model assessment for insulin resistance (-0·4 (sd 1·3) v. +1·1 (sd 2·7), P=0·003) and homoeostatic model assessment for β cell function (-5·1 (sd 24·2) v. +18·9 (sd 45·6), P=0·008) and a significant increase in quantitative insulin sensitivity check index (+0·01 (sd 0·01) v. -0·007 (sd 0·02), P=0·02). In addition, synbiotic intake significantly decreased serum TAG (-14·8 (sd 56·5) v. +30·4 (sd 37·8) mg/dl, P<0·001) and VLDL-cholesterol concentrations (-3·0 (sd 11·3) v. +6·1 (sd 7·6) mg/dl, P<0·001) compared with the placebo. Overall, the results of this study demonstrate that taking synbiotic supplements for 6 weeks among patients with GDM had beneficial effects on markers of insulin metabolism, TAG and VLDL-cholesterol concentrations.

THE EFFECTS OF PROBIOTIC AND SELENIUM CO-SUPPLEMENTATION ON MENTAL HEALTH PARAMETERS AND METABOLIC PROFILES IN TYPE 2 DIABETIC PATIENTS WITH CORONARY HEART DISEASE: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL.

Clin Nutr. 2018 Jul 21. pii: S0261-5614(18)31219-6. doi: 10.1016/j.clnu.2018.07.017. [Epub ahead of print]

Raygan F et al.

Abstract

BACKGROUND AND AIMS:

The objective of this investigation was to assess the effects of probiotic and selenium co-supplementation on indicators of mental health and metabolic profiles in diabetic people with coronary heart disease (CHD).

METHODS:

This randomized, double-blind, placebo-controlled trial was conducted among 54 diabetic people with CHD. Patients were randomly allocated into two groups to receive either 200 μg/day selenium plus 8×10^9 CFU/day probiotic (n = 27) or placebo (n = 27) for 12 weeks.

RESULTS:

Probiotic and selenium co-supplementation significantly decreased Beck Depression Inventory index (β -1.46; 95% CI, -2.61, -0.31; P = 0.01) and Beck Anxiety Inventory index (β -1.23; 95% CI, -2.33, -0.12; P = 0.02) compared with the placebo. Consuming probiotic plus selenium lowered fasting plasma glucose (β -10.80 mg/dL; 95% CI, -17.68, -3.92; P = 0.003), serum insulin levels (β -3.42 μIU/mL; 95% CI, -4.93, -1.90; P < 0.001), insulin resistance (β -0.96; 95% CI, -1.45, -0.47; P < 0.001), and enhanced insulin sensitivity (β 0.01; 95% CI, 0.007, 0.01; P < 0.001) compared with the placebo. Additionally, co-supplementation reduced triglycerides (β -34.45 mg/dL; 95% CI, -56.18, -12.72; P = 0.003), VLDL- (β -6.89 mg/dL; 95% CI, -11.23, -2.54; P = 0.003), total cholesterol (β -18.13 mg/dL; 95% CI, -23.42, -2.83; P = 0.02) and high sensitivity C-reactive protein (β -1043.28 ng/mL; 95% CI, -1929.67, -156.89; P = 0.02), and increased nitric oxide (β 7.86 μmol/L; 95% CI, 5.63, 10.09; P < 0.001), total antioxidant capacity (β 119.30 mmol/L; 95% CI, 63.04, 175.57; P < 0.001) and total glutathione (β 154.16 μmol/L; 95% CI, 82.57, 225.74; P < 0.001) compared with the placebo.

CONCLUSIONS:

Probiotic and selenium co-supplementation to diabetic people with CHD improved indicators of mental health and metabolic profiles. Registered under Clinical Trials.gov Identifier no. http://www.irct.ir: IRCT20170513033941N28.

EFFECT OF PROBIOTICS ON GLUCOSE AND LIPID METABOLISM IN TYPE 2 DIABETES MELLITUS: A META-ANALYSIS OF 12 RANDOMIZED CONTROLLED TRIALS.

Med Sci Monit. 2017 Jun 22;23:3044-3053.

Yao K et al

Abstract

BACKGROUND It has been unclear whether supplemental probiotics therapy improves clinical outcomes in type 2 diabetic patients. This meta-analysis aimed to summarize the effect of probiotics on glucose and lipid metabolism and C-reactive protein (CRP) from 12 randomized controlled trials (RCTs). MATERIAL AND METHODS An up-to-date search was performed for all relevant RCTs up to April 2016 from PubMed, Embase, and Cochrane Library. Standardized mean difference (SMD) and weighted mean difference (WMD) were calculated for a fixed-effect and random-effect meta-analysis to assess the impact of supplemental probiotics on fasting plasma glucose (FPG), glycated hemoglobin (HbA1c), fasting insulin, homeostasis model assessment of insulin resistance (HOMA-IR), lipid profile, and CRP level. RESULTS A total of 12 studies (684 patients) were entered into the final analysis. The effect of probiotics was significant on reducing HbA1c level (standardized mean difference [SMD], -0.38; confidence interval [CI], -0.62 to -0.14, P=0.002; I^2=0%, P=0.72 for heterogeneity), fasting insulin level (SMD, -0.38; CI -0.59 to -0.18, P=0.0003; I^2=0%, P=0.81 for heterogeneity), and HOMA-IR (SMD, -0.99; CI -1.52 to -0.47, P=0.0002; I^2=86%, P<0.00001 for heterogeneity). Pooled results on effects of probiotics on FPG, CRP, or lipid profile were either non-significant or highly heterogeneous. CONCLUSIONS This meta-analysis demonstrated that probiotics supplementation was associated with significant improvement in HbA1c and fasting insulin in type 2 diabetes patients. More randomized placebo-controlled trials with large sample sizes are warranted to confirm our conclusions.

EFFECTIVENESS OF PROBIOTICS IN TYPE 2 DIABETES: A META-ANALYSIS.

Pol Arch Med Wewn. 2015;125(11):803-13. Epub 2015 Oct 2.

Kasińska MA, Drzewoski J.

Abstract

INTRODUCTION:

An increasing number of studies suggest that the use of probiotics may have a beneficial effect in patients with type 2 diabetes.

OBJECTIVES:

The aim of the study was to assess the ability of probiotics to modify selected cardiometabolic risk factors in subjects with type 2 diabetes.

METHODS:

PubMed, Embase, Cochrane Library, and Scopus databases were thoroughly reviewed up to January 2015 to search for randomized controlled trials (RCTs) that examined the effect of probiotics on selected modifiable cardiometabolic parameters in patients with type 2 diabetes. The following endpoints were considered: fasting plasma glucose (FPG), insulin concentration, insulin resistance, hemoglobin A1c (HbA1c), as well as the levels of total cholesterol, triglycerides, low-density and high-density lipoprotein cholesterols, and C-reactive protein (CRP). A total of 571 RCTs were initially identified, of which 8 trials with 438 individuals were selected for meta-analysis. The effects of probiotics were calculated for each parameter.

RESULTS:

The meta-analysis showed a significant effect of probiotics on reducing HbA1c levels (standardized mean difference [SMD], -0.81; confidence interval [CI], -1.33 to -0.29, P = 0.0023; I2 = 68.44%; P = 0.0421 for heterogeneity) and HOMA-IR (SMD, -2.10; CI -3.00 to -1.20, P <0.001; I2 = 82.91%; P = 0.0029 for heterogeneity). Supplementation with probiotics did not have a significant effect on FPG, insulin, and CRP levels as well as the lipid profile.

CONCLUSIONS:

Our meta-analysis suggests that probiotic supplementation might improve, at least to some extent, metabolic control in subjects with type 2 diabetes. However, larger well-designed, longterm RCTs are needed to confirm any potentially beneficial relationship between the use of probiotics and modifiable cardiometabolic risk factors in patients with type 2 diabetes.

GLUCOSE- AND GLYCEMIC FACTOR-LOWERING EFFECTS OF PROBIOTICS ON DIABETES: A META-ANALYSIS OF RANDOMISED PLACEBO-CONTROLLED TRIALS.

Br J Nutr. 2016 Apr 14;115(7):1167-77. doi: 10.1017/S0007114516000076. Epub 2016 Feb 22.

Sun J[1], Buys NJ[2].

Abstract

This meta-analysis examined the effect of probiotics on glucose and glycaemic factors in diabetes and its associated risk factors. All randomised-controlled trials published in English in multiple databases from January 2000 to June 2015 were systematically searched. Only studies that addressed glucose- and glycaemic-related factors as outcome variables were included. The main outcomes of interest in trials were mean changes in glucose, HbA1c, insulin and homoeostasis model assessment-estimated insulin resistance (HOMA-IR). Using the Physiotherapy Evidence Database (PEDro) scale to assess the quality of studies, a total of eleven studies with 614 subjects were included. The pooled mean difference and effect size with a 95% CI were extracted using a random-effect model. It was found that there are statistically significant pooled mean differences between the probiotics and the placebo-controlled groups on the reduction of glucose (-0·52 mmol/l, 95% CI -0·92, -0·11 mmol/l; P=0·01) and HbA1c (-0·32%, 95% CI -0·57, -0·07%; P=0·01). There was no statistically significant pooled mean difference between the probiotics and the placebo-controlled groups on the reduction of insulin (-0·48 μIU/ml, 95% CI -1·34, 0·38 μIU/ml; P=0·27) and HOMA-IR (pooled effect of -0·44, 95% CI -1·57, 0·70; P=0·45). Meta-regression analysis identified that probiotics had significant effects on reduction of glucose, HbA1c, insulin and HOMA-IR in participants with diabetes, but not in participants with other risk factors. The present meta-analysis suggested that probiotics may be used as an important dietary supplement in reducing the glucose metabolic factors associated with diabetes.

EFFECT OF PROBIOTICS ON GLUCOSE METABOLISM IN PATIENTS WITH TYPE 2 DIABETES MELLITUS: A META-ANALYSIS OF RANDOMIZED CONTROLLED TRIALS

Medicina (Kaunas). 2016;52(1):28-34. doi: 10.1016/j.medici.2015.11.008. Epub 2015 Dec 29.

Zhang Q et al

Abstract

OBJECTIVE:

Our aim was to investigate the effects of probiotics on glucose metabolism in patients with type 2 diabetes mellitus using a meta-analysis of randomized, controlled trials.

MATERIALS AND METHODS:

Online databases Embase, Web of Science, and PubMed were searched until August 2014 to identify eligible articles. Finally, 7 trials were included.

RESULTS:

Probiotic consumption significantly changed fasting plasma glucose (FPG) by -15.92mg/dL (95% confidence interval [CI], -29.75 to -2.09) and glycosylated hemoglobin (HbA1c) by -0.54% (95% CI, -0.82 to -0.25) compared with control groups. Subgroup analysis was conducted to trials with non-yogurts control. Meta-analysis of trials with multiple species of probiotics found a significant reduction in FPG (weighted mean difference [WMD]: -35.41mg/dL, 95% CI: -51.98 to -18.89). The duration of intervention for ≥8 weeks resulted in a significant reduction in FPG (WMD: -20.34mg/dL, 95% CI: -35.92 to -4.76). Subgroup analysis of trials with species of probiotics did not result in a significant meta-analysis effect. Furthermore, the duration of intervention <8 weeks did not result in a significant reduction in FPG. The results also showed that probiotic therapy significantly decreased homeostasis model assessment of insulin resistance (HOMA-IR) and insulin concentration (WMD: -1.08, 95% CI: -1.88 to -0.28; and WMD: -1.35mIU/L, 95% CI: -2.38 to -0.31, respectively).

CONCLUSIONS:

The present meta-analysis suggests that consuming probiotics may improve glucose metabolism by a modest degree, with a potentially greater effect when the duration of intervention is ≥8 weeks, or multiple species of probiotics are consumed.

THE EFFECTS OF PROBIOTICS SUPPLEMENTATION ON METABOLIC HEALTH IN PREGNANT WOMEN: AN EVIDENCE BASED META-ANALYSIS.

PLoS One. 2018 May 21;13(5):e0197771. doi: 10.1371/journal.pone.0197771. eCollection 2018.

Zheng J[1] et al

Abstract

The prevalence of maternal obesity and gestational diabetes mellitus (GDM) is increasing rapidly. Probiotics supplementation have been shown to improve metabolic health in humans. In our study, we aimed to evaluate the effects of probiotics supplementation on metabolic health and pregnancy complications in pregnant women. The literature search, data extraction and quality assessment were performed, and data were synthesized in accordance with standardized guidelines. Ten randomized clinical trials with eligible data were included in our meta-analysis. For pregnant women with GDM, we found negative correlations between probioticssupplementation and fasting serum insulin (OR -2.94, 95%CI [-5.69, -0.20], p = 0.04) and homoeostasis model assessment for insulin resistance (HOMA-IR) (OR -0.65, 95%CI [-1.18, -0.11], p = 0.02). There were no significant correlations between probioticssupplementation and lipid levels in women with GDM, including total cholesterol (OR -2.72, 95%CI [-17.18, 11.74], P = 0.71), high density lipoprotein cholesterol (HDL-c) (OR -0.29, 95%CI [-3.60, 3.03], P = 0.87), low density lipoprotein cholesterol (LDL-c) (OR -0.38, 95%CI [-18.54, 17.79], P = 0.97), or triglycerides (OR -12.83, 95%CI [-36.63, 10.97], P = 0.29). For healthy pregnant women, probiotics supplementation were negatively associated with fasting serum insulin (OR -3.76, 95%CI [-4.29, -3.23], P < 0.00001) and HOMA-IR (OR -0.57, 95%CI [-1.08, -0.06], p = 0.03). However, no significant correlations were observed between probioticssupplementation and fasting plasma glucose (FPG) (OR -2.02, 95%CI [-5.56, 1.52], p = 0.26). Thus, our study revealed that probiotics supplementation during pregnancy have beneficial effects on glucose metabolism, rather than lipid metabolism among pregnant women.

HUMAN CLINICAL STUDIES: EFEECT OF PROBIOTICS ON BRAIN AND OTHER CENTRAL NERVOUS SYSTEM

IMPACT OF CONSUMING A MILK DRINK CONTAINING A PROBIOTIC ON MOOD AND COGNITION.

Eur J Clin Nutr. 2007 Mar;61(3):355-61. Epub 2006 Dec 6.

Benton D et al

Abstract

OBJECTIVE:

The impact on mood and memory of consuming a probiotic containing milk drink, or a placebo, was examined as, previously, a poor mood has been found to correlate with the frequency of constipation.

DESIGN:

A double-blind placebo-controlled trial with random allocation of subjects.

SETTING:

Subjects went about their normal life in the community apart from three visits to the laboratory.

SUBJECTS:

One hundred and thirty-two healthy members of general population, mean age 61.8 years, volunteered in response to local media coverage. One hundred and twenty-four finished the trial.

INTERVENTION:

For a 3-week period, either a probiotic containing milk drink, or a placebo, were consumed daily. Mood and cognition were measured at baseline, and after 10 and 20 days of consumption.

RESULTS:

At baseline those who reported themselves to be less frequently constipated were more clearheaded, confident and elated. Although the taking of the probiotic did not generally change the mood, this appeared to be a reflection of the generally good mood in this sample. When those in the bottom third of the depressed/elated dimension at baseline were considered, they selectively responded by reporting themselves as happy rather than depressed after taking the probiotic. The intervention did not, however, influence the reported frequency of defaecation, probably a reflection of the initially low incidence of constipation. An unexpected and possibly chance finding was that the consumption of probiotics resulted in a slightly-poorer performance on two measures of memory.

CONCLUSIONS:

The consumption of a probiotic-containing yoghurt improved the mood of those whose mood was initially poor. This improvement in mood was not, however, associated with an increased frequency of defaecation.

EVIDENCES OF A NEW PSYCHOBIOTIC FORMULATION ON BODY COMPOSITION AND ANXIETY.

Mediators Inflamm. 2017;2017:5650627. doi: 10.1155/2017/5650627. Epub 2017 Sep 24.

Colica C et al

Abstract

BACKGROUND:

Gut microbiota is implied in obesity, because of its ability to harvest energy from diet, and in the regulation of behavior. Given the link between gut microbiota, body composition, obesity, and anxiety, the aim of this study was to evaluate the effects of a new psychobiotic formulation.

METHODS:

Eligible patients were randomly divided into three groups: psychobiotics oral suspension group (POSG); dietary treatment group (DTG); combined treatment group (CTG). All subjects underwent body composition and psychological profile evaluation.

RESULTS:

Significant changes in body composition parameters in each group were relieved after all treatments. Hamilton anxiety rating scale (HAM-A) highlighted a significant reduction of the total score for all study population after treatments in POSG ($p = 0.01$) and CTG ($p = 0.04$). A reduction of HAM-A total score in anxious subjects in POSG or CTG and a significant reduction of positive subjects for HAM-A in POSG ($p = 0.03$) and in CDG ($p = 0.01$) were shown.

DISCUSSION:

Three-week intake of selected POS represents a good approach to solve problems related to obesity and behavior disorders. However, new clinical trials need to be performed on a larger population and for a longer period of treatment before definitive conclusions can be made. This trial is registered with NCT01890070.

A RANDOMIZED CONTROLLED TRIAL TO TEST THE EFFECT OF MULTISPECIES PROBIOTICS ON COGNITIVE REACTIVITY TO SAD MOOD.

Brain Behav Immun. 2015 Aug;48:258-64. doi: 10.1016/j.bbi.2015.04.003. Epub 2015 Apr 7.

Steenbergen L et al

Abstract

BACKGROUND:

Recent insights into the role of the human microbiota in cognitive and affective functioning have led to the hypothesis that probiotic supplementation may act as an adjuvant strategy to ameliorate or prevent depression.

OBJECTIVE:

Heightened cognitive reactivity to normal, transient changes in sad mood is an established marker of vulnerability to depression and is considered an important target for interventions. The present study aimed to test if a multispecies probiotic containing Bifidobacterium bifidum W23, Bifidobacterium lactis W52, Lactobacillus acidophilus W37, Lactobacillus brevis W63, Lactobacillus casei W56, Lactobacillus salivarius W24, and Lactococcus lactis (W19 and W58) may reduce cognitive reactivity in non-depressed individuals.

DESIGN:

In a triple-blind, placebo-controlled, randomized, pre- and post-intervention assessment design, 20 healthy participants without current mood disorder received a 4-week probiotic food-supplement intervention with the multispecies probiotics, while 20 control participants received an inert placebo for the same period. In the pre- and post-intervention assessment, cognitive reactivity to sad mood was assessed using the revised Leiden index of depression sensitivity scale.

RESULTS:

Compared to participants who received the placebo intervention, participants who received the 4-week multispecies probiotics intervention showed a significantly reduced overall cognitive reactivity to sad mood, which was largely accounted for by reduced rumination and aggressive thoughts.

CONCLUSION:

These results provide the first evidence that the intake of probiotics may help reduce negative thoughts associated with sad mood. Probiotics supplementation warrants further research as a potential preventive strategy for depression.

BACILLUS COAGULANS MTCC 5856 FOR THE MANAGEMENT OF MAJOR DEPRESSION WITH IRRITABLE BOWEL SYNDROME: A RANDOMISED, DOUBLE-BLIND, PLACEBO CONTROLLED, MULTI-CENTRE, PILOT CLINICAL STUDY.

Food Nutr Res. 2018 Jul 4;62. doi: 10.29219/fnr.v62.1218. eCollection 2018.

Majeed M et al

Abstract

BACKGROUND:

The modification of microbial ecology in human gut by supplementing probiotics may be an alternative strategy to ameliorate or prevent depression.

OBJECTIVE:

The current study was conducted to assess the safety and efficacy of the probiotic strain *Bacillus coagulans* MTCC 5856 for major depressive disorder (MDD) in IBS patients.

METHOD:

Patients (n = 40) diagnosed for MDD with IBS were randomized (1:1) to receive placebo or *B. coagulans* MTCC 5856 at a daily dose of 2 × 109 cfu (2 billion spores) and were maintained to the end of double-blind treatment (90 days). Changes from baseline in clinical symptoms of MDD and IBS were evaluated through questionnaires.

RESULTS:

Significant change (p = 0.01) in favour of the *B. coagulans* MTCC 5856 was observed for the primary efficacy measure Hamilton Rating Scale for Depression (HAM-D), Montgomery-Asberg Depression Rating Scale (MADRS), Center for Epidemiological Studies Depression Scale (CES-D) and Irritable bowel syndrome quality of life questionnaire (IBS-QOL). Secondary efficacy measures i.e. Clinical Global Impression-Improvement rating Scale (CGI-I), Clinical Global Impression Severity rating Scale (CGI-S), Gastrointestinal Discomfort Questionnaire (GI-DQ) and Modified Epworth Sleepiness Scale (mESS) also showed significant results (p = 0.01) in *B. coagulans* MTCC 5856 group compared to placebo group except dementia total reaction scoring. Serum myeloperoxidase, an inflammatory biomarker was also significantly reduced (p < 0.01) when compared with the baseline and end of the study. All the safety parameters remained well within the normal clinical range and had no clinically significant difference between the screening and at the end of the study.

CONCLUSION:

B. coagulans MTCC 5856 showed robust efficacy for the treatment of patients experiencing IBS symptoms with major depressive disorder. The improvement in depression and IBS symptoms was statistically significant and clinically meaningful. These findings support *B. coagulans* MTCC 5856 as an important new treatment option for major depressive disorder in IBS patients.

Fermented milk of *Lactobacillus helveticus*IDCC3801 improves cognitive functioning during cognitive fatigue tests in healthy older adults

Journal of Functional Foods, 10: 465-474, (2014)

Young-ChulChung

Abstract

Probiotics are consumed in a wide variety of fermented foods to improve health. This study was conducted to investigate the effects of *Lactobacillus helveticus*-fermented milk (LHFM), on cognitive function in healthy older adults. A 12-week, double-blind, randomized controlled experiment was conducted. Cognitive tests (neuropsychological and cognitive fatigue) and measurements of the perceived stress scale (PSS), geriatric depression scale-short form (GDS-SF), brain-derived neurotrophic factor (BDNF) and whole blood viscosity (WBV) were conducted before and after the experiment. The administration of LHFM for 12 weeks in healthy older adults produced improvement on cognitive tests compared to the placebo group. However, no significant effects were observed for PSS, GDS-SF, BDNF, and WBV. Thus, consumption of LHFM might be beneficial for improving cognitive function.

EFFECT OF LACTOBACILLUS RHAMNOSUS HN001 IN PREGNANCY ON POSTPARTUM SYMPTOMS OF DEPRESSION AND ANXIETY: A RANDOMISED DOUBLE-BLIND PLACEBO-CONTROLLED TRIAL

EBioMedcine 24, October 2017, 159-165

R.F.Slykerman

Abstract

Background

Probiotics may help to prevent symptoms of anxiety and depression through several putative mechanisms.

Objective

The aim of this study was to evaluate the effect of *Lactobacillus rhamnosus* HN001 (HN001) given in pregnancy and postpartum on symptoms of maternal depression and anxiety in the postpartum period. This was a secondary outcome, the primary outcome being eczema in the offspring at 12 months of age.

Design, Setting, Participants

A randomised, double-blind, placebo-controlled trial of the effect of HN001 on postnatal mood was conducted in 423 women in Auckland and Wellington, New Zealand. Women were recruited at 14–16 weeks gestation.

Intervention

Women were randomised to receive either placebo or HN001 daily from enrolment until 6 months postpartum if breastfeeding.

Outcome Measures

Modified versions of the Edinburgh Postnatal Depression Scaleand State Trait Anxiety Inventory were used to assess symptoms of depression and anxiety postpartum.

Trial Registration

Australia NZ Clinical Trials Registry: ACTRN12612000196842.

Findings

423 women were recruited between December 2012 and November 2014. 212 women were randomised to HN001 and 211 to placebo. 380 women (89.8%) completed the questionnaire on psychological outcomes, 193 (91.0%) in the treatment group and 187 (88.6%) in the placebo group. Mothers in the probiotic treatment group reported significantly lower depression scores (HN001 mean = 7·7 (SD = 5·4), placebo 9·0 (6·0); effect size -1·2, (95% CI -2·3, -0·1), p = 0·037) and anxiety scores (HN001 12·0 (4·0), placebo 13·0 (4·0); effect size -1·0 (-1·9, -0·2), p = 0·014) than those in the placebo group. Rates of clinically relevant anxiety on screening (score > 15) were significantly lower in the HN001 treated mothers (OR = 0·44 (0·26, 0·73), p = 0·002).

Interpretation

Women who received HN001 had significantly lower depression and anxiety scores in the postpartum period. This probiotic may be useful for the prevention or treatment of symptoms of depression and anxiety postpartum.

CLINICAL AND METABOLIC RESPONSE TO PROBIOTIC ADMINISTRATION IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL.

Nutrition. 2016 Mar;32(3):315-20. doi: 10.1016/j.nut.2015.09.003. Epub 2015 Sep 28.

Akkasheh G et a;

Abstract

OBJECTIVE:

We are aware of no study examining the effects of probiotic supplementation on symptoms of depression, metabolic profiles, serum high-sensitivity C-reactive protein (hs-CRP), and biomarkers of oxidative stress in patients with major depressive disorder (MDD). The present study was designed to determine the effects of probiotic intake on symptoms of depression and metabolic status in patients with MDD.

METHODS:

This randomized, double-blind, placebo-controlled clinical trial included 40 patients with a diagnosis of MDD based on DSM-IV criteria whose age ranged between 20 and 55 y. Patients were randomly allocated into two groups to receive either probiotic supplements (n = 20) or placebo (n = 20) for 8 wk. Probiotic capsule consisted of three viable and freeze-dried strains: Lactobacillus acidophilus (2 × 10(9) CFU/g), Lactobacillus casei (2 × 10(9) CFU/g), and Bifidobacterium bifidum (2 × 10(9) CFU/g). Fasting blood samples were taken at the beginning and end of the trial to quantify the relevant variables. All participants provided three dietary records (two weekdays and one weekend) and three physical activity records during the intervention.

RESULTS:

Dietary intake of study participants was not significantly different between the two groups. After 8 wk of intervention, patients who received probiotic supplements had significantly decreased Beck Depression Inventory total scores (-5.7 ± 6.4 vs. -1.5 ± 4.8, P = 0.001) compared with the placebo. In addition, significant decreases in serum insulin levels (-2.3 ± 4.1 vs. 2.6 ± 9.3 μIU/mL, P = 0.03), homeostasis model assessment of insulin resistance (-0.6 ± 1.2 vs. 0.6 ± 2.1, P = 0.03), and serum hs-CRP concentrations (-1138.7 ± 2274.9 vs. 188.4 ± 1455.5 ng/mL, P = 0.03) were observed after the probiotic supplementation compared with the placebo. Additionally, taking probiotics resulted in a significant rise in plasma total glutathione levels (1.8 ± 83.1 vs. -106.8 ± 190.7 μmol/L, P = 0.02) compared with the placebo. We did not find any significant change in fasting plasma glucose, homeostatic model assessment of beta cell function, quantitative insulin sensitivity check index, lipid profiles, and total antioxidant capacity levels.

CONCLUSIONS:

Probiotic administration in patients with MDD for 8 wk had beneficial effects on Beck Depression Inventory, insulin, homeostasis model assessment of insulin resistance, hs-CRP concentrations, and glutathione concentrations, but

did not influence fasting plasma glucose, homeostatic model assessment of beta cell function, quantitative insulin sensitivity check index, lipid profiles, and total antioxidant capacity levels.

A RANDOMIZED CONTROLLED TRIAL TO TEST THE EFFECT OF MULTISPECIES PROBIOTICS ON COGNITIVE REACTIVITY TO SAD MOOD.

Brain Behav Immun. 2015 Aug;48:258-64. doi: 10.1016/j.bbi.2015.04.003. Epub 2015 Apr 7.

Steenbergen L et al

Abstract

BACKGROUND:

Recent insights into the role of the human microbiota in cognitive and affective functioning have led to the hypothesis that probiotic supplementation may act as an adjuvant strategy to ameliorate or prevent depression.

OBJECTIVE:

Heightened cognitive reactivity to normal, transient changes in sad mood is an established marker of vulnerability to depression and is considered an important target for interventions. The present study aimed to test if a multispecies probiotic containing Bifidobacterium bifidum W23, Bifidobacterium lactis W52, Lactobacillus acidophilus W37, Lactobacillus brevis W63, Lactobacillus casei W56, Lactobacillus salivarius W24, and Lactococcus lactis (W19 and W58) may reduce cognitive reactivity in non-depressed individuals.

DESIGN:

In a triple-blind, placebo-controlled, randomized, pre- and post-intervention assessment design, 20 healthy participants without current mood disorder received a 4-week probiotic food-supplement intervention with the multispecies probiotics, while 20 control participants received an inert placebo for the same period. In the pre- and post-intervention assessment, cognitive reactivity to sad mood was assessed using the revised Leiden index of depression sensitivity scale.

RESULTS:

Compared to participants who received the placebo intervention, participants who received the 4-week multispecies probiotics intervention showed a significantly reduced overall cognitive reactivity to sad mood, which was largely accounted for by reduced rumination and aggressive thoughts.

CONCLUSION:

These results provide the first evidence that the intake of probiotics may help reduce negative thoughts associated with sad mood. Probiotics supplementation warrants further research as a potential preventive strategy for depression.

A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED TRIAL OF LACTOBACILLUS HELVETICUS AND BIFIDOBACTERIUM LONGUM FOR THE SYMPTOMS OF DEPRESSION.

Aust N Z J Psychiatry. 2017 Aug;51(8):810-821. doi: 10.1177/0004867416686694. Epub 2017 Jan 10.

Romijn AR et al

Abstract

OBJECTIVES:

This trial investigated whether probiotics improved mood, stress and anxiety in a sample selected for low mood. We also tested whether the presence or severity of irritable bowel syndrome symptoms, and levels of proinflammatory cytokines, brain-derived neurotrophic factor and other blood markers, would predict or impact treatment response.

METHOD:

Seventy-nine participants (10 dropouts) not currently taking psychotropic medications with at least moderate scores on self-report mood measures were randomly allocated to receive either a probiotic preparation (containing Lactobacillus helveticus and Bifidobacterium longum) or a matched placebo, in a double-blind trial for 8 weeks. Data were analysed as intent-to-treat.

RESULTS:

No significant difference was found between the probiotic and placebo groups on any psychological outcome measure (Cohen's d range = 0.07-0.16) or any blood-based biomarker. At end-point, 9 (23%) of those in the probiotic group showed a ⩾60% change on the Montgomery-Åsberg Depression Rating Scale (responders), compared to 10 (26%) of those in the placebo group ([Formula: see text], p = ns). Baseline vitamin D level was found to moderate treatment effect on several outcome measures. Dry mouth and sleep disruption were reported more frequently in the placebo group.

CONCLUSIONS:

This study found no evidence that the probiotic formulation is effective in treating low mood, or in moderating the levels of inflammatory and other biomarkers. The lack of observed effect on mood symptoms may be due to the severity, chronicity or treatment resistance of the sample; recruiting an antidepressant-naive sample experiencing mild, acute symptoms of low mood, may well yield a different result. Future studies taking a preventative approach or using probiotics as an adjuvant treatment may also be more effective. Vitamin D levels should be monitored in future studies in the area. The results of this trial are preliminary; future studies in the area should not be discouraged.