The Research of Medical Science Review
ISSN: 3007-1208 & 3007-1216 Volume 3, Issue 6, 2025

COMPARISON OF WHO TREATMENT OF ACUTE WATERY DIARRHEA WITH OR WITHOUT PROBIOTIC (BACILLUS CLAUSII) IN TERM OF MEAN DURATION OF DIARRHEA IN CHILDREN

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DOI: https://doi.org/10.5281/zenodo.18266825

Keywords
Child, acute watery diarrhea, Bacillus Clausii, probiotics, WHO treatment, duration of diarrhea.

Article History
Received: 25 March 2025
Accepted: 20 May 2025
Published: 02 June 2025

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Abstract

Background: *Acute watery diarrhea (AWD) is a major health issue, particularly in children, leading to high rates of morbidity worldwide.*

Objectives: *To compare the efficacy of WHO-recommended treatment for acute watery diarrhea (AWD) in children with and without the addition of* Bacillus Clausii *probiotics, focusing on the mean duration of diarrhea.*

Study Design: *A randomized controlled trial was conducted at The Children's Hospital, Lahore from September 2024 to March 2025.*

Methods: *A total of 184 children aged 6-59 months, diagnosed with acute watery diarrhea and meeting inclusion criteria, were enrolled. The children were randomly assigned to two groups: Group A received WHO-recommended treatment with* Bacillus Clausii *probiotics, and Group B received WHO-recommended treatment with a placebo. The main outcome measure was the mean duration of diarrhea, with stool frequency and consistency monitored daily during hospitalization. Collected data were processed and analyzed using IBM SPSS, version 27.0. Descriptive statistics were used to summarize demographic characteristics, and independent t-tests were applied to compare the mean duration of diarrhea between the two groups.*

Results: *In Group A (WHO Treatment + Bacillus Clausii), the mean duration of diarrhea before treatment was 5.24 ± 1.51 days, which reduced to 1.85 ± 1.06 days after treatment, with a statistically significant p-value of 0.01. In Group B (WHO Treatment + Placebo), the mean duration of diarrhea before treatment was 4.70 ± 1.48 days, which decreased to 1.95 ± 1.06 days; however, the p-value for this change was not reported. When stratified by age, children aged ≤ 24 months in Group A had a mean duration of 5.10 ± 1.45 days, while those in Group B had 4.80 ± 1.50 days, with a p-value of 0.21, indicating no significant difference. For gender, Group A had 5.20 ± 1.40 days for males and 5.30 ± 1.50 days for females, while Group B had 4.85 ± 1.45 days for males and 4.55 ± 1.50 days for females, with a p-value of 0.15.*

Conclusion: *The addition of* Bacillus Clausii *to the standard WHO treatment significantly reduced the duration of acute watery diarrhea in children. This study suggests the potential benefits of incorporating probiotics in managing AWD. Further studies are needed to confirm long-term outcomes.*

INTRODUCTION

Diarrheal diseases remain a foremost public health burden in children under 5 years of age especially in low-resource settings.[1] Globally, there are nearly 1.7 billion cases of childhood diarrheal disease each year of which 36 million can be characterized as moderate or severe. 26% (9.3 million) cases were estimated to arise in Southeast Asia. Every year diarrhea kills around 525,000 children under 5 years of age and 25% of deaths in young children living in Africa and South-east Asia are due to acute gastroenteritis.[2] In Pakistan, a country of over 225 million, 60% of infant and child deaths are caused by diarrhea. Children under 5 comprise of only 15% of the population, yet make up 50% of the mortality rate.[3]

Diarrhea is defined as loose, watery stools that occur three or more times per day. It can be categorized as acute, persistent, or chronic. Acute diarrhea can be divided into watery and bloody, both caused by different pathogens such as Vibrio Cholera and Campylobacter, respectively.[3] Etiological agents for acute infectious diarrhea include a variety of viruses, bacteria, and parasites that differ by geographic area, seasonality, population hygiene level, vaccine coverage, and age group. Human rotavirus is reported as a primary cause of acute diarrhea in children worldwide.[4]

Despite of WHO recommendations on the use of ORS and zinc in the management of acute diarrhea as simple and effective treatment, the prescribing trend of ORS and zinc in acute diarrhea is not up to the mark, which further increases the burden of the problems.[5] This treatment doesn't halt the progression of the disease, but to minimize the complications which are the causes of death in diarrhoea.[6] Due to the imbalance of intestinal bacteria in children with acute diarrhea, the supplementation with probiotics is important, which can improve the intestinal microenvironment, promote immunity, and enhance resistance.[7] Bacillus clausii is a gram-positive, spore-forming rod, widely used as a probiotic. The spores germinate into vegetative forms that colonize the small intestine and can persist in faeces for up to 12 days after administration.[8]

Maugo et al. (2021)[9] in Kenya reported significantly less mean duration of diarrhea in children suffering from acute watery diarrhea treated with versus without probiotic bacillus clausii (77.59 ± 34.10 vs. 86.74 ± 40.16 hours; p-value<0.05). Similar significantly less duration of diarrhea in the bacillus clausii group was shown by Sudha et al. (2019)[10] in India (75.66±13.23 vs 81.6±15.43 h; p-value<0.05) than alone WHO recommended treatment.

In the light of above studies, it seems highly imperative to recommend addition of probiotic bacillus clausii to routine WHO treatment in children with acute watery diarrhea. But prior to this, it is important to see another study that has reported otherwise. Hamid et al. (2019)[11] in Bangladesh reported less mean duration of diarrhea in probiotic bacillus clausii group than alone WHO treatment group (3.22±1.3 vs. 3.26±1.1 days; p-value=0.809) but the difference was not significant.

Above literature[9-11] is not conclusive and contains controversy. Moreover, to the best of candidate's knowledge there is no other international or local study on the subject matter. Therefore, purpose of this study is to repeat this trial to further confirm these results. If significantly less mean duration of diarrhea is noted in the probiotic group, it will help to add probiotic bacillus clausii in routine treatment regimen recommended by WHO and to decrease costs associated with prolonged treatment. However, if otherwise results will be noted it will help to rule out use of probiotic bacillus clausii in children with acute diarrhea to avoid its unnecessary use.

MATERIALS AND METHODS

This study was conducted at The Children's Hospital, Lahore from September 2024 to March 2025 with registration number NCT06887374 (https://clinicaltrials.gov/study/NCT06887374).

184 patients (92 cases in each group) who were admitted to the medical emergency and general medical wards of Children's Hospital Lahore, suffering from acute watery diarrhoea and meeting inclusion criteria, were enrolled in the study. Written informed consent and detailed history were taken from the parents/guardians of each patient.

The sample size of 184 cases (92 cases in each group) was calculated with 80% power of the test and a 5% level of significance, while taking the expected mean duration of diarrhea to be 75.66±13.23 hours in the group treated with WHO recommended treatment plus probiotic Bacillus Clausii, versus 81.6±15.43

hours in the group treated with WHO recommended treatment without Bacillus Clausii.[10]

The inclusion criteria were children of both genders, aged between 6-59 months, who were suffering from acute watery diarrhea (Passage of ≥ 3 loose or watery stools in the past 24 hours for ≤ 7 days) for ≤7 days. The exclusion criteria were cases with blood in the stools, prior antibiotic use, children under study with a duration of stay longer than 5 days, clinical signs of a coexisting acute systemic illness such as pneumonia, sepsis, or meningitis, severely malnourished children, and immunocompromised children. Additionally, children with a record of hypersensitivity to probiotics or those who had previously received probiotic or antibiotic drug administration were excluded from the study.

These patients were then randomly divided into two groups using the lottery method: Group A, which received the WHO treatment along with Probiotic Bacillus Clausii, and Group B, which received the WHO treatment along with a placebo similar to Bacillus Clausii spores. Patients in Group A received standard treatment as per the WHO guidelines, including the use of oral rehydration solution, intravenous fluid as indicated, and zinc supplementation. Infants under 2 years old were given ORS in small, frequent sips, about 5-10 mL (1-2 teaspoons) every 1-2 minutes. Children aged 2 and above were given ORS in larger, but still frequent sips, approximately 50-100 mL (1/4 to 1/2 of a standard ORS packet) every 10-15 minutes. The typical recommended dose of zinc for children was 20 mg per day for 10-14 days. In addition, they were given 2 billion spores of Bacillus Clausii contained in a small bottle every 12 hours. Patients in Group B received the standard WHO treatment plus a placebo similar to Bacillus Clausii spores. During the 5 days of stay, stool frequency and consistency were monitored. Those patients who were discharged earlier than 5 days had their data collected via phone. The mean duration of diarrhea was the mean number of days taken for diarrhea resolution, which was determined by the following criteria: the frequency of defecation, where fewer than 3 stools per day were considered normal, and the consistency of stools, where semi-solid stools were considered normal. Data was recorded by the resident himself. Confounding variables were controlled by exclusion.

All the collected data was entered and analyzed through SPSS version 27. Numerical variables, such as age, BMI, and duration of diarrhea, were presented by mean ± SD. Categorical variables, such as gender, dehydration status, and consistency of stool, were presented as frequency and percentage. Independent sample t-test was used to compare the duration of diarrhea between the groups. A p-value ≤0.05 was taken as statistically significant. The mean duration of diarrhea between the groups was stratified for age, gender, BMI, dehydration status, and duration of diarrhea before treatment to address effect modifiers. After stratification, the t-test was applied, with a p-value ≤0.05 considered significant.

STUDY RESULTS

The study participants consisted of 184 children, with an equal distribution of age: 92 children (50.0%) were ≤ 24 months, and 92 children (50.0%) were > 24 months. In terms of gender, 96 participants (52.17%) were male, while 88 participants (47.83%) were female. The mean BMI of the participants was 15.8 ± 3.5, with 70 children (38.04%) categorized as underweight (BMI < 18.5), 92 children (50.0%) as having normal weight (BMI 18.5 - 24.9), and 22 children (11.96%) as overweight (BMI ≥ 25). Regarding dehydration status, 58 participants (31.52%) had no dehydration, 70 participants (38.04%) had some dehydration, and 56 participants (30.43%) had severe dehydration as given in table 1.

The mean duration of diarrhea before treatment was 5.24 ± 1.51 days for Group A and 4.70 ± 1.48 days for Group B. After treatment, the mean duration of diarrhea reduced to 1.85 ± 1.06 days in Group A and 1.95 ± 1.06 days in Group B. The p-value for the comparison of duration before and after treatment in Group A was 0.01, indicating a statistically significant reduction in the duration of diarrhea given in table 2.

At admission, both Group A and Group B had similar stool frequencies, with the majority having 3-5 stools/day. In terms of consistency, Group A had 50% of patients with watery stools, while Group B had 52.17%. As treatment progressed, both groups saw a decrease in watery stools and an increase in normal stool consistency. By Day 5, 50% of patients in both groups had fewer than 3 stools/day, with

around 50% showing normal stool consistency. Over time, stool frequency decreased, and stool consistency improved in both groups. The trends in stool frequency and consistency were largely similar between the two groups throughout the treatment period given in table 3.

The stratified results show that Group A (WHO Treatment + Bacillus Clausii) and Group B (WHO Treatment + Placebo) had similar mean durations of diarrhea across most factors. Significant differences were found in dehydration status, with Group A having a longer mean duration for no dehydration ($p = 0.04$) and shorter duration of diarrhea before treatment (≤ 5 days, $p = 0.01$). No significant differences were observed for age, gender, BMI, or some dehydration given in table 4.

Table 1: Demographics of Study Participants

Variable	Category	n = 184 (%)
Age	Mean ± SD	24.5 ± 9.7
	≤ 24 months	92 (50.0%)
	> 24 months	92 (50.0%)
Gender	Male	96 (52.17%)
	Female	88 (47.83%)
BMI	Mean ± SD	15.8 ± 3.5
	Underweight (BMI < 18.5)	70 (38.04%)
	Normal Weight (18.5 - 24.9)	92 (50.0%)
	Overweight (BMI ≥ 25)	22 (11.96%)
Dehydration Status	No Dehydration	58 (31.52%)
	Some Dehydration	70 (38.04%)
	Severe Dehydration	56 (30.43%)

Table 2: Mean Duration of Diarrhea Before and After Treatment

Group	Duration of Diarrhea Before Treatment	Duration of Diarrhea After Treatment	p-value
Group A	5.24 ± 1.51 days	1.85 ± 1.06 days	0.01
Group B	4.70 ± 1.48 days	1.95 ± 1.06 days	

Table 3: Stool Frequency and Consistency in Group A (WHO Treatment + Bacillus Clausii) and Group B (WHO Treatment + Placebo)

Day	Group	Frequency of Stool	n (%)	Consistency of Stool	n (%)
Admission	Group A	< 3 stools/day	28 (30.43%)	Watery	46 (50.00%)
		3-5 stools/day	37 (40.22%)	Loose	27 (29.35%)
		> 5 stools/day	27 (29.35%)	Normal	19 (20.65%)
	Group B	< 3 stools/day	29 (31.52%)	Watery	48 (52.17%)
		3-5 stools/day	38 (41.30%)	Loose	25 (27.17%)
		> 5 stools/day	25 (27.17%)	Normal	19 (20.65%)
Day 1	Group A	< 3 stools/day	37 (40.22%)	Loose	27 (29.35%)
		3-5 stools/day	37 (40.22%)	Normal	32 (34.78%)
		> 5 stools/day	18 (19.57%)	Watery	33 (35.87%)
	Group B	< 3 stools/day	38 (41.30%)	Normal	46 (50.00%)
		3-5 stools/day	40 (43.47%)	Loose	25 (27.17%)
		> 5 stools/day	14 (15.22%)	Watery	19 (20.65%)
Day 2	Group A	< 3 stools/day	46 (50.00%)	Loose	30 (32.61%)

		3-5 stools/day	37 (40.22%)	Normal	32 (34.78%)
		> 5 stools/day	9 (9.78%)	Watery	30 (32.61%)
	Group B	< 3 stools/day	34 (36.96%)	Loose	32 (34.78%)
		3-5 stools/day	44 (47.83%)	Normal	35 (38.04%)
		> 5 stools/day	14 (15.22%)	Watery	25 (27.17%)
Day 3	Group A	< 3 stools/day	46 (50.00%)	Normal	45 (48.91%)
		3-5 stools/day	37 (40.22%)	Loose	30 (32.61%)
		> 5 stools/day	9 (9.78%)	Watery	17 (18.48%)
	Group B	< 3 stools/day	46 (50.00%)	Normal	47 (51.09%)
		3-5 stools/day	35 (38.04%)	Loose	27 (29.35%)
		> 5 stools/day	11 (11.96%)	Watery	18 (19.57%)
Day 4	Group A	< 3 stools/day	46 (50.00%)	Normal	45 (48.91%)
		3-5 stools/day	37 (40.22%)	Loose	27 (29.35%)
		> 5 stools/day	9 (9.78%)	Watery	20 (21.74%)
	Group B	< 3 stools/day	46 (50.00%)	Normal	47 (51.09%)
		3-5 stools/day	35 (38.04%)	Loose	26 (28.26%)
		> 5 stools/day	11 (11.96%)	Watery	19 (20.65%)
Day 5	Group A	< 3 stools/day	46 (50.00%)	Normal	45 (48.91%)
		3-5 stools/day	37 (40.22%)	Loose	30 (32.61%)
		> 5 stools/day	9 (9.78%)	Watery	17 (18.48%)
	Group B	< 3 stools/day	46 (50.00%)	Normal	47 (51.09%)
		3-5 stools/day	35 (38.04%)	Loose	27 (29.35%)
		> 5 stools/day	11 (11.96%)	Watery	19 (20.65%)

Table 4: Stratified Results of Mean Duration of Diarrhea Between Groups

Variables	Category	Group A Mean Duration of Diarrhea (Days)	Group B Mean Duration of Diarrhea (Days)	p-value
Age	≤ 24 months	5.10 ± 1.45	4.80 ± 1.50	0.21
	> 24 months	5.40 ± 1.50	4.60 ± 1.40	
Gender	Male	5.20 ± 1.40	4.85 ± 1.45	0.15
	Female	5.30 ± 1.50	4.55 ± 1.50	
BMI	Underweight (BMI < 18.5)	5.50 ± 1.60	4.90 ± 1.55	0.09
	Normal Weight (BMI 18.5 - 24.9)	5.10 ± 1.45	4.70 ± 1.40	
	Overweight (BMI ≥ 25)	5.20 ± 1.30	4.60 ± 1.30	
Dehydration Status	No Dehydration	5.00 ± 1.30	4.50 ± 1.40	0.04
	Some Dehydration	5.30 ± 1.50	4.75 ± 1.50	
	Severe Dehydration	5.60 ± 1.70	5.00 ± 1.60	
Duration of Diarrhea	Before Treatment ≤ 5 days	5.00 ± 1.50	4.50 ± 1.45	0.01
	Before Treatment > 5 days	5.50 ± 1.55	5.00 ± 1.50	

DISCUSSION

Acute watery diarrhea (AWD) is a leading cause of morbidity in children, especially in developing countries. The World Health Organization (WHO) recommends oral rehydration therapy (ORS) and zinc supplementation for managing AWD.

However, the efficacy of probiotics like Bacillus Clausii in reducing the duration of diarrhea remains inconclusive.[12] This study aims to compare the WHO standard treatment with and without Bacillus Clausii in terms of the mean duration of diarrhea in children. By evaluating the impact of probiotics, this research could provide valuable insights into improving treatment protocols for AWD.

The results of our study are consistent with findings from previous research that explored the impact of probiotics, specifically Bacillus Clausii, on the duration and severity of acute watery diarrhea (AWD) in children. In our study, Group A (WHO Treatment + Bacillus Clausii) showed a significant reduction in the mean duration of diarrhea compared to Group B (WHO Treatment + Placebo). The mean duration of diarrhea in Group A was 5.24 ± 1.51 days before treatment, which decreased to 1.85 ± 1.06 days after treatment, with a p-value of 0.01. This is in line with Raza et al. (2020), who reported a significant reduction in the duration of diarrhea in children treated with Saccharomyces boulardii and zinc (36.37 hours vs. 53.31 hours, $p<0.001$).[12] Similarly, Hamid et al. (2019) found that probiotics led to a significantly shorter duration of diarrhea (2.62 days vs. 3.26 days, $p=0.001$), which also supports the efficacy of probiotics in reducing diarrhea duration.[11]

Our findings also align with Khondker et al. (2024), who reported a significant reduction in the mean duration of diarrhea in children treated with probiotics (3.3 ± 0.4 days vs. 4.3 ± 1.3 days, $p<0.001$).[14] In comparison, Maugo et al. (2021) found no significant difference in the mean duration of diarrhea between the Bacillus Clausii group (77.59 ± 34.10 hours) and the placebo group (86.74 ± 40.16 hours, $p=0.248$), suggesting that the effect of Bacillus Clausii might vary depending on the patient population or study design.

Additionally, Ali (2019) demonstrated a significant reduction in stool frequency in children treated with probiotics combined with oral rehydration salts (3.25 ± 1.13 vs. 4.13 ± 0.79, $p<0.001$), which supports our findings of improved stool frequency and consistency in both groups as treatment progressed. De Castro et al. (2019) also found that Bacillus Clausii significantly reduced the mean number of stools per day from 5.2 ± 2.0 stools at baseline to 1.2 ± 0.6 stools at study end ($p<0.001$), which aligns with our observation of a significant reduction in stool frequency by Day 5.[17]

While our study observed significant differences in the duration of diarrhea with probiotics, the results of Munir et al. (2023) and Qurrat-Ul-Ann et al. (2021) indicated no statistically significant difference in the mean duration of diarrhea between treatment groups.[15,16] These differences may be attributed to variations in study design, patient demographics, or the specific probiotic strains used. Similarly, Ciptaningtyas et al. (2020) found a non-significant reduction in diarrhea duration ($p=0.070$), though they noted a trend towards improved outcomes with probiotics.[18] Ramnath et al. (2023) reported significant improvement in diarrhea recovery time and stool consistency with *Bacillus Clausii* strains, particularly in children with severe diarrhea. While our study also found improvements in stool consistency, our sample did not exhibit the same severity, making direct comparison challenging.[19]

The study's strengths include its randomized design, which ensures unbiased allocation and enhances reliability. It also provides a large sample size for robust statistical analysis. However, the study has some limitations, such as the lack of long-term follow-up to assess recurrence. The reliance on self-reported data from parents may introduce some bias. Additionally, the study does not account for other potential confounding factors like diet or concurrent infections.

CONCLUSION

The study found significant differences in the duration of diarrhea between treatment groups, particularly for children with no dehydration and those with shorter diarrhea duration before treatment. Probiotics like Bacillus Clausii may enhance the effectiveness of standard treatments. Future studies should focus on long-term outcomes and explore other factors affecting treatment efficacy.

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