ResearchArticle

DOI: http://dx.doi.org/10.53043/2347-3894.acam90050

Effect of β-Glucan (Angel Yeast) Compared to a Placebo on Cold and Flu Incidence and Symptoms in an Adult Population – A Double Blind, Randomised Controlled Trial

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Asian Journal of Complementary and Alternative Medicine. Volume 10 Issue 05

Published on: 19/12/2022

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Cite this article as: Briskey D, Rao A. *Effect of β-Glucan (Angel Yeast) Compared to a Placebo on Cold and Flu Incidence and Symptoms in an Adult Population – A Double Blind, Randomised Controlled Trial.* Asian Journal of Complementary and Alternative Medicine, Vol 10(5), 173-180:2022.

ABSTRACT

Background: β-1, 3/1, 6-glucan derived from Baker's yeast (*Saccharomyces cerevisiae*) is a widely studied and documented β-glucan known for its immune stimulatory efficacy, mode of action, and safety. Previous research indicates that it may have an effect on reducing symptoms of cold and flu. The current study aimed to examine the effects of yeast β-glucan (Angel Yeast) on cold and flu incidences and symptoms in a healthy adult population.

Methods: Two hundred and thirty-one males and females aged between 18 and 65 years old completed 3 months of supplementation with either β-glucan or a placebo. Participants completed a general health questionnaire throughout the trial period and recorded any incidences of cold and flu symptoms.

Results: β-glucan supplementation reduced the self-reported severity of sore throats and improved sleep quality.

Conclusions: Yeast β-glucan was shown to be safe and tolerable, with results indicating it can reduce the severity of a sore throat experienced during a cold or flu episode.

Keywords: Yeast β-glucan; *Saccharomyces cerevisiae;* Upper respiratory tract infection

INTRODUCTION

The common cold is one of the most prevalent infectious diseases in humans. The common cold is a mild, self-limiting catarrhal illness associated with a low-grade fever. It is not a single entity, but a clinical syndrome caused by a variety of different viruses [1]. Of these, rhinoviruses and coronaviruses are responsible for approximately 50 to 70% of all colds expressed in human populations [2-4]. Adults can average 2 to 4 colds per year, and children 6 to 10 per year, depending on age and exposure [5]. Therefore, for most individuals, a reduction in symptom severity and/or duration is a reasonable substitute for an outright cure.

Several natural products have been touted as being able to reduce symptoms and/or duration of cold episodes [6]. One compound studied for its efficacy is β-glucans. β-glucans are a heterogenous group of natural polysaccharides found in cereal grains, several mushrooms, algae, bacteria, plants, and fungi [7-9]. The most characterised and effective source of β-glucan are those extracted from the cell wall of Baker's yeast (*Saccharomyces cerevisiae*) [8,10,11]. Baker's yeast β-glucan, having a (1,3)-β core chain with (1,6)-β branching [12], is known to have a high biological activity and thus potent immunostimulatory effect [13] due to its insolubility [9], structural complexity [14], and high degree of side-chain branching [12,13,15].

The main therapeutic mechanisms of Baker's yeast β-glucan are increasing host resistance against bacterial, viral, fungal, and parasitic infections, and suppressing the progression of carcinogenesis [12]. While Baker's yeast derived β-glucan primarily enhances the innate immune response [13,16], it can also promote adaptive immunity, thereby priming the body to counter foreign pathogens [9,17]. Importantly,

it is purported to regulate the immune system without inducing damaging inflammatory reactions by upregulating both infection fighting and immunoregulatory molecules [13,18]. Several studies have investigated the effect of 1-3, 1-6 β-glucan on upper respiratory tract infections (URTI's) using a variety of doses [16,19-23]. Studies have found that orally supplemented β-glucan URTI occurrence, symptom severity, and stress levels compared to placebo in healthy participants with recurring infections [16,17,19,24-28]. The aim of this study was to assess the effectiveness of β-glucan for reducing incidence and severity of cold and flu symptoms compared to a placebo in otherwise healthy adults.

METHODS

A double-blind, randomised controlled trial with a three-month intervention. This study was a remote study (using telehealth visits), with participants recruited from across Australia. Eligible participants were provided with a copy of the participant information sheet, underwent full screening against the inclusion and exclusion criteria, and given a full explanation of the trial and their requirements. Eligible participants gave their electronic written consent and were randomly allocated to either the active β-glucan group (200 mg daily taken in the morning of Angel Yeast beta glucan, containing a minimum of 85% (1,3)-(1,6)-β-D-glucan; provided by Angel Yeast Co., Ltd.) or placebo group (200 mg maltodextrin taken daily in the morning). Group allocation was conducted using Random Allocation Software by an individual who was not involved in the trial. Both the participant and investigator were blinded to the treatment allocated. Of the 352 people screened, 240 participants were enrolled in the study (Figure 1).

Participants were included in the study if they met the criteria detailed in Table 1.

Once enrolled, participants completed a SF-8 health survey questionnaire and again every 4 weeks during the three-month trial period. Upon the onset of cold and flu symptoms (i.e., cough, sneezing, stuffy or runny nose, fever, scratchy or sore throat, and nasal breathing), participants recorded their daily symptoms (including severity) online using the WURSS-24 (Wisconsin Upper Respiratory Symptom Survey 24) questionnaire until symptoms subsided. Once symptoms subsided, participants continued taking their trial product and recorded any subsequent episodes provided they were symptom free for at least 2 weeks.

The primary outcome for this study was the number of cold and flu incidences. Secondary outcomes included change in cold or flu duration and severity (WURSS-24), change in general health [Short Form 8 (SF-8)], product tolerance and/or adverse events, days off work, and rescue medication use.

Table 1: Inclusion and exclusion criteria used for participant screening.

Inclusion
• Male or female aged between 18 and 65 years old who were able to provide informed consent, • Agreeing not to take any β-glucan supplement or other supplements or medications aimed at preventing UTRI's for the duration of the study period.
Exclusion
• Unstable or serious illness (kidney, liver, GIT, heart conditions, diabetes, thyroid gland function, malignancy, lung conditions, or chronic asthma), • Anyone regularly (>3 times per week) consuming unprocessed food high in β-glucan or with added β-glucan, • Acute sickness experienced in the past 2 months, • Serious mood disorders or neurological disorders, • People with cognitive damage, • People who have or have had treatment for cancer, HIV, or chronic use of steroids in the past year, • Active smokers and/or nicotine or drug abuse, • Chronic alcohol use (>14 alcoholic drinks per week), • Allergic to any of the ingredients in the active or placebo formula, • Pregnant or lactating women, • Participants medically prescribed medication that would affect the immune and/or inflammatory response, • Participants who had participated in any other related clinical study during the past month, • Any condition that the investigator deemed made the participant unsuitable for inclusion.

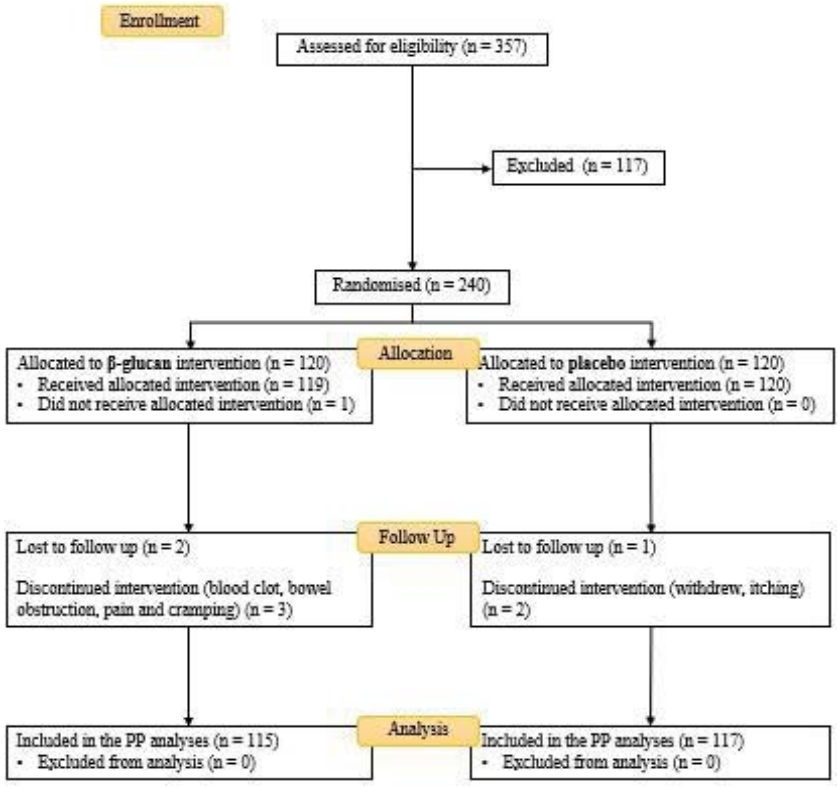

Figure 1: Participant flow diagram.

Power analysis indicated that to achieve statistical power, 33 cold and flu incidents were required per group for power to detect a change of 25% in cold and flu incidence between groups (α error probability of 0.05 and powered to 0.95, effect size d=0.82). Therefore, 240 participants were recruited with the aim to achieve a minimum of 70 cold and flu events (30 in the active group and 40 in the placebo group).

Statistical analyses were performed using IBM SPSS Statistics (version 25.0) for Windows (IBM, Chicago, IL, USA). Differences between number of cold episodes per group was assessed using Chi Squared tests and changes in cold severity and impact was analysed using Wilcoxon rank-sum (Mann-Whitney) tests. Statistical significance was set at $p \leq 0.05$. Subgroup analysis was conducted on symptom outcome measures from the WURSS-24 for only trial participants that reported experiencing that particular symptom during a reported event (i.e. any score of zero was excluded from analysis).

The study was performed in accordance with the current version of the Declaration of Helsinki (52nd WMA General Assembly, Edinburgh, Scotland, October 2000). The trial was conducted in agreement with the International Conference on Harmonisation (ICH) guidelines on Good Clinical Practice. The study protocols were approved by Bellberry Ltd Human Research and Ethics Committee (2020-06-603).

This study was conducted in Australia, with participants starting the study between November (Summer) 2020 and May (Autumn/Fall) 2021 and completing the study by September (Spring) 2021.

RESULTS

There was no statistical difference between the active and placebo groups for baseline demographics (Table 2). Both groups presented with approximately twice as many females as males, typically aged in their 30's–40's with average height, weight and a healthy BMI (Table 2).

Table 2: Summary of participant baseline demographics.

Parameters	**β-glucan (*n* = 119)**	**Placebo (*n* = 120)**
Male (*n*)	39	36
Female (*n*)	80	84
Age (years)	38.5 ± 11.4	40.4 ± 10.5
Height (m)	1.68 ± 0.10	1.68 ± 0.97
Weight (kg)	76.29 ± 23.73	76.00 ± 20.49
Body Mass Index (kg/m^2)	26.80 ± 8.10	26.87 ± 5.94

One person in the β-glucan group was removed due to withdrawing prior to starting. Values represented as mean ± SD

There was no statistical difference between groups for the number of participants from each group that completed the study (Table 3). A total of 8 people discontinued during the study. Three participants were lost to follow-up (2 in active and 1 in placebo group), 4 withdrew due to adverse events deemed not related to the study [3 in the active group (1 developed a blood clot, 1 a bowel obstruction and 1 stomach pain and cramping) and 1 in the placebo group (itching)] and 1 withdrew with no reason provided.

There was no statistical difference between the active and placebo groups for the number or duration of the illness reported (Table 3). There was no statistical difference between the active and placebo groups for the average days sick or the number of days taken off work due to sickness (Table 3).

Data from all trial participants showed there was a statistically significant difference between groups for sleeping well from the WURSS-24 (Table 4). No other significant differences were found from the WURSS-24 for all trial participants.

Table 3: Trial event outcome measures.

	β-glucan (active)	**Placebo**	***p* – value (Chi squared)**
Completed study (*n*)	115	117	
Cold episodes reported (*n*)	24	23	
Total days in study (*n*)	10530	10530	
Total days sick (*n*)	141	148	
Sick (%)	20.86	19.65	0.853
Days sick (%)	1.34	1.43	0.798
Average days sick	5.88 ± 3.04	6.43 ± 3.47	0.559
Days off work	0.29 ± 0.55	0.70 ± 1.06	0.053

Table 4: Symptom outcome measures for all trial participants reporting an event.

Parameter	**β-glucan (*n* = 24) Median (interquartile range)**	**Placebo (*n* = 23) Median (interquartile range)**	***p* - value**
Runny nose	5.5 (12)	6 (9)	0.748
Plugged nose	5 (12)	8 (18)	0.839
Sneezing	2 (4)	2 (5)	0.966
Sore throat	6.5 (15)	12 (10)	0.088
Scratchy throat	4.5 (10)	7 (12)	0.276
Cough	6 (10)	6 (11)	0.579
Hoarseness	3.5 (9)	2 (11)	1.000
Head congestion	3 (16)	6 (14)	0.423
Chest congestion	0 (3)	1 (11)	0.239
Feeling tired	8 (23)	10 (16)	0.424
Headache	4 (12)	6 (12)	0.248
Body aches	2 (14)	4 (12)	0.686
Fever	0 (1)	0 (2)	0.58
Total symptoms	56 (126)	77 (120)	0.183
Think clearly	4 (13)	6 (10)	0.398
Sleep well	4 (17)	13 (15)	0.039*
Breathe easily	5 (13)	4 (14)	0.643
Walk, climb stairs, exercise	1 (13)	5 (13)	0.559
Accomplish daily activities	1 (12)	6 (13)	0.193
Work outside the home	0.5 (11)	4 (13)	0.343
Work inside the home	1 (11)	2 (11)	0.513
Interact with others	3.5 (12)	4 (14)	0.730
Live your personal life	2.5 (14)	6 (13)	0.337
Total impact	26.5 (119)	47 (111)	0.142

Values represented as severity, * significantly different from placebo ($p < 0.05$).

The symptom outcome measure for trial participants who reported the symptom during an event showed a significant difference between groups for sore throats (Table 5).

The results of the SF-8 general health questionnaire showed the only significant difference over time or treatment group between groups was for question 7 at baseline with the placebo group recording a higher core than the β-glucan group (Table 6). Overall, compliance for capsule consumption this study was high and equal for both groups, with 96.1% and 95.2% for the active and placebo groups, respectively.

Of the 240 participants that were randomised for this trial, 231 completed the full intervention period (Figure 1), with one person in the β-glucan group recording an event prior to withdrawal and were therefore included in the analysis. Within the active treatment group, one participant withdrew before starting, two were lost to follow up, two suffered serious adverse events (blood clot and bowel obstruction) unrelated to the trial product, and one withdrew due to an adverse event (pain and cramping) that may have been related to the trial product. In the placebo group, one participant was lost to follow up, one withdrew due to personal reasons, and one withdrew due to reported adverse events (eczema unrelated to the trial product and itching that may have been caused by the trial product).

DISCUSSION

The current study assessed the efficacy of β-glucan (Angel Yeast) on cold and flu symptoms in healthy adults. Overall, β-glucan was shown to be safe and tolerable amongst participants. Results indicate β-glucan was able to reduce the severity of a sore throat experienced during a cold or flu episode, which is supported by existing literature [29]. The purported mechanism of action for decreasing severity is the recognition of β-glucan by Dectin-1 receptors, triggering phagocytosis and the production of proinflammatory factors and leading to the elimination of infectious agents, such as those causing sore throats [13].

A recent study [26] showed supplementation with a yeast derived 1-3, 1-6 glucopolysaccharide was able to significantly improve breathing in participants, however, as with the present study, other trending factors were found, including total number of days with URTI symptoms (p=0.06). In the current study, it was found

Table 5: Symptom outcome measures for trial participant data reporting that symptom during a reported event.

Parameter	*n*	β-glucan Median (interquartile range)	*n*	Placebo Median (interquartile range)	*p* - value
Runny nose	19	8 (9)	19	6 (14)	0.644
Plugged nose	20	5 (12)	17	13 (19)	0.117
Sneezing	21	2 (4)	18	3.5 (8)	0.335
Sore throat	22	5.5 (9)	20	12 (15)	0.037*
Scratchy throat	19	4 (10)	21	7 (11)	0.258
Cough	19	7 (10)	20	5.5 (11)	0.857
Hoarseness	14	7.5 (11)	15	3 (14)	0.234
Head congestion	20	3 (15)	19	11 (14)	0.258
Chest congestion	9	3 (12)	14	6 (13)	0.688
Feeling tired	21	8 (21)	23	9 (18)	0.991
Headache	18	5.5 (11)	20	7 (12)	0.478
Body aches	16	6.5 (16)	14	4 (18)	0.294
Fever	6	4 (8)	7	5 (7)	0.445
Total symptoms	24	46.5 (126)	23	48 (69)	0.709
Think clearly	18	5 19)	20	6 (9)	0.988
Sleep well	19	5 (19)	22	12 (15)	0.313
Breathe easily	19	6 (12)	15	9 (11)	0.891
Walk, climb stairs, exercise	14	7.5 (18)	14	7.5 (13)	0.603
Accomplish daily activities	17	4 (16)	18	6.5 (13)	0.195
Work outside the home	12	9 (15)	14	9 (14)	0.527
Work inside the home	14	4 (13)	16	4 (10)	0.854
Interact with others	17	6 (9)	16	9.5 (15)	0.26
Live your personal life	16	3.5 (12)	17	7 (12)	0.326
Total impact	23	24 (62)	23	47 (111)	0.079

Values represented as severity, * significantly different from placebo (p<0.05).

Table 6: SF-8 outcomes for all trial participants.

	Baseline		Month 3		Change from baseline	
	β-glucan	Placebo	β-glucan	Placebo	β-glucan	Placebo
1.Overall, how would you rate your health during the past 4 weeks.	80.0 ± 16.8	79.3 ± 16.4	77.0 ± 15.1	75.7 ± 16.4	-0.88 ± 17.40	-3.54 ± 18.56
2. During the past 4 weeks, how much did physical health problems limit your physical activities (such as walking or climbing stairs)?	89.5 ± 15.8	85.9 ± 22.8	85.7 ± 20.2	86.4 ± 19.3	-3.76 ± 21.19	0.88 ± 27.94
3. During the past 4 weeks, how much difficulty did you have doing your daily work, both at home and away from home, because of your physical health?	92.0 ± 12.6	90.8 ± 16.6	90.6 ± 16.8	89.0 ± 16.9	-1.99 ± 18.64	-1.77 ± 17.27
4. How much bodily pain have you had during the past 4 weeks?	82.2 ± 16.0	82.2 ± 19.8	82.3 ± 17.2	81.2 ± 19.3	-0.53 ± 16.14	-0.71 ± 18.11
5. During the past 4 weeks, how much energy did you have?	70.6 ± 15.8	70.1 ± 16.2	68.2 ± 19.2	67.9 ± 16.1	-2.88 ± 19.41	-2.21 ± 16.21
6. During the past 4 weeks, how much did your physical health or emotional problems limit your usual social activities with family or friends?	87.6 ± 17.8	88.9 ± 16.9	84.2 ± 21.1	85.7 ± 19.8	-3.98 ± 24.68	-2.65 ± 19.01
7. During the past 4 weeks, how much have you been bothered by emotional problems (such as feeling anxious, depressed or irritable)?	78.2 ± 21.0*	83.5 ± 18.0	78.5 ± 20.2	78.7 ± 21.7	-0.22 ± 20.73	-3.98 ± 21.80
8. During the past 4 weeks, how much did personal or emotional problems keep you from doing your usual work, school or other daily activities	88.2 ± 18.1	91.2 ± 15.2	84.9 ± 19.6	89.4 ± 16.2	-3.98 ± 20.48	-1.11 ± 16.16

Values are presented as mean ± SD; * significantly different from placebo group (p<0.05).

that overall symptom score in those reporting symptoms trended towards significance (p=0.08). The current study also found the measure of sleep well was significantly improved in the β-glucan groups compared to the placebo (Table 4). However, when data was analysed only for those participants that reported sleep difficulties, the significance was lost. Therefore, further studies may be required to investigate the effect β-glucan has on sleep. It is likely that β-glucan is able to affect sleep quality more from improving other symptoms, such as the sore throat, than directly affecting any physiological aspect of the sleep cycle. Other studies have also shown varied results, including reduction in overall URTI symptom score and reduced sleep difficulties, however, these studies have been performed on specialised population groups, such as marathon runners and stressed women [19,28,29].

Another trend found in the present study was a reduction in days taken off work. The β-glucan group had less than half the time off work compared to the placebo, with 0.3 days compared with 0.7 days, respectively (p=0.053). There are, however, other factors that are difficult to take into consideration with this result, including work conditions, environment, location, and leave availability, that make it difficult to compare, with so few events reported. COVID-19 may also have been a factor in reported days off, with many people working from home and able to work even when experiencing some cold and flu like symptoms.

A major limitation with this study was that it was conducted during COVID-19. During this period, the majority of people were isolating and/or taking safety measures, such as hand sanitation and face masks, to avoid transmission and/or infections. As a result, fewer people than expected experienced a cold or flu event during the trial period. Furthermore, due to people being less active in the community (self-isolation at home), there was a greater opportunity for people to rest and recover faster than what may occur otherwise. The effects of these factors may have on the results are unable to be determined.

Dosage is another factor that may have affect the results of this study. The dose used (200 mg per day) was amongst the lowest reported for studies investigating the effects of β-glucan [30]. Whilst several studies had tested doses at 250 mg per day [20-23], some studies have investigated doses as high as 900 mg per day [16,19]. The difference a higher dosage may have had on the results, however, is unknown, with studies using a higher dose also having variable results and often focusing on different cohorts, for example, marathon runners [22,23].

Future research on the effects of β-glucan may benefit from using a larger number of participants. One study recruited 100 people and reported 24 events [26], whilst the present study recruited 240 people and reported 47 events. With both studies reporting a trend towards significance for several outcomes, a larger cohort may be required to reach the power necessary to achieve significance. Future research may also benefit from

investigating a higher daily dose or a split dose, where participants consume a capsule in the morning and one in the evening. A split dose protocol may help to boost the immune response by maintaining a higher blood concentration for a greater proportion of the day.

Overall, yeast β-glucan was shown to be safe and tolerable, with results indicating it can reduce the severity of a sore throat experienced during a cold or flu episode.

FUNDING

This study was funded by Angel Yeast Co., Ltd.

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