Evaluation of the efficacy and safety of PartySmart in the prevention of alcohol-induced hangover: A prospective, randomized, double blind, comparative, crossover, phase III clinical trial

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ABSTRACT
This study was planned to evaluate the comparative efficacy and safety of "PartySmart", a polyherbal formulation in the prevention of the alcohol-induced hangover symptoms, with one of other formulations, promoted as a cure for alcohol-induced hangover.

The present study was a prospective, randomized, double blind, comparative, crossover, phase III clinical trial. The duration of the study was 12 hours on 2 different nights, separated by a week of washout period. A total of 20 healthy male participants, who were occasional social alcohol drinkers were included in the study. All the volunteers were assessed at baseline, and at 2 and 10 hours after receiving the study formulations, for the physical changes, and for blood and urinary alcohol and acetaldehyde levels. The POMS questionnaire was used to evaluate the intensity of hangover. As per the crossover design, the participants received the opposite treatment after a week of washout period, following the same procedure.

This study observed a highly significant difference in the mean final hangover score (which was higher in the "Compared formulation" group, as compared to the PartySmart group), and in the mean blood alcohol levels after 10 hours, the mean blood acetaldehyde levels after 2 and 10 hours, mean urinary alcohol levels after 10 hours, and the mean urinary

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acetaldehyde levels after 10 hours. There were no clinically significant adverse reactions, either observed by investigators or reported by the volunteers, and overall compliance was good. Therefore, it may be concluded that, "PartySmart" is effective and safe in the prevention of the alcohol-induced hangover symptoms, and is more effective than the "Compared formulation".

INTRODUCTION

‘Hangover: Monday Blues!’

“Suicide hangs in the air, a fat, rain-filled cloud; dirty orange sun; Vain and ugly tears through tattered curtains;

Covered in yellow nicotine stains, antique cancer;

Crawling up and into what was once a delicate white!

Smoke lolls and dips, dances sultry;

The ones widows wear, to hide my nickel and dime eyes!

I pull up the blankets, blocking out the ignorant sunshine;

Slip back into the safe and easy confines of ‘night!’"¹

Despite its long history, little is known about the physiology of hangover, the degree to which hangover affects a person’s thinking and motor functions; and hangover prevention and treatment. Though, there are some formulations are promoted as a cure for alcohol-induced hangover; but the claims have not been substantiated with evidence from clinical trials.²

"PartySmart" is a polyherbal formulation recommended for the prevention of alcohol-induced hangover, and it contains the extracts of Phoenix dactylifera, Cichorium intybus, Andrographis paniculata, Vitis vinifera, Phyllanthus amarus, and Emblica officinalis. Previous studies have shown that pre-treatment with "PartySmart", was associated with rapid elimination of alcohol and acetaldehyde, and prevention of hangover symptoms.³⁻⁵

This study was planned to evaluate the efficacy and safety of "PartySmart" in the prevention of the alcohol-induced hangover symptoms, with one formulation, which is promoted as a cure for alcohol-induced hangover. This formulation, with which the activity of PartySmart was compared, has a serving size of 2 tablets, and the amount per serving contains Fumaric acid (100 mg), Succinic acid (250 mg), L-glutamine (250 mg), L-cysteine (15 mg), Dextrose (250 mg), Young barley grass juice powder (75 mg), and Vitamins C (45 mg), B-1 (2 mg), B-12 (1200 mcg) and Folic acid (400 mcg).

Aim of the study

This study was planned to evaluate the comparative efficacy and safety of "PartySmart", with the "Compared formulation", on blood and urinary levels of alcohol and acetaldehyde after alcohol ingestion, and in the prevention of the alcohol-induced hangover.

Study design

Present study was a prospective, randomized, double blind, comparative, crossover, phase III clinical trial. The duration of the study was 12 hours on 2 different nights, separated by a week’s washout period, and the ‘Institutional Ethics Committee’ approved the study.

MATERIALS AND METHODS

Inclusion criteria

A total of 20 healthy male participants, from the pool of volunteers, who were occasional social alcohol drinkers, aged between 25 to 45 years, and who were willing to give informed consent were included in the study.

Exclusion criteria

Exclusion criteria were volunteers with acid peptic disorder, diabetes mellitus, neurological disorders and psychiatric disorders, history of drug abuse, history of alcohol abuse, and a score of more than 2 points on the validated brief Michigan Alcoholism Screening Test (MAST).⁶ Similarly, volunteers consuming certain concomitant medications like antibiotics (furazolidone, griseofulvin and imidazoles), anticoagulants (warfarin), tricyclic antidepressants, antihistamines, anticonvulsants (phenytoin), cardiovascular medications (nitroglycerin, reserpine, methyldopa, hydralazine and guanethidine), sedatives and hypnotics (benzodiazepines), and those volunteers, who had known hypersensitivity to alcohol were excluded from the study.

Randomization and blinding

A person unconnected with the study did randomization by using computer generated random number allocation. Double blinding was done, and neither the volunteers, nor the investigators were aware of the treatment allocation.

Study drugs

Randomly allocated volunteers were divided into 2 groups: the "Party Smart" group, and the "Compared formulation" group. The PartySmart group received a capsule of "PartySmart" (Batch No. 41/2/R&D/HDC/2004), and the "Compared formulation" group was given the other formulation, which has serving size of 2 tablets. The recommended dose of the "Compared formulation" is 2 tablets per two alcoholic drinks (either before or during alcohol consumption); and the volunteers from the "Compared formulation" group consumed the formulation as per the recommended dose.

Study procedure

All the volunteers were instructed to refrain from consuming any alcoholic
beverages at least 48 hours before the study. To induce hangover symptoms, but prevent excessive drinking, all the volunteers were asked to quantify their usual alcohol consumption. All the volunteers were also asked to quantify their usual alcohol consumption that will reliably result in hangover symptoms the next day, based on their previous personal experience.

All the volunteers were assessed at baseline (before taking the study formulations), and at 2 and 10 hours after receiving the formulations; for physical changes, and for blood and urinary alcohol and acetaldehyde levels. The alcohol and acetaldehyde levels were measured by gas chromatography (Micro-9100, NETEL Chromatograph). The investigators supervised the intake of the "PartySmart" capsules and the Compared formulation by the volunteers.

All the participants ate their food from the same restaurant, where they consumed the same type of food, on each of the 2 study days, after consuming alcohol. To prevent over drinking, all the participants were reminded to limit their alcohol consumption to a predefined quantity. All the participants consumed same brand and type of alcohol (48 w/v, 75% proof whisky), and the details of the number of alcoholic drinks consumed by each volunteer, the time of ‘going to bed’ and ‘rising in the morning’ were recorded in a structured CRF. Local accommodation and taxi transfer were provided to all the participants.

There are various studies done on psychoactive drugs and also on alcohol-induced hangover using the POMS questionnaire. The POMS questionnaire measures the effects on mood of various therapeutic approaches, and an abbreviated version, which included 12 questions, was used for this study. The volunteers were asked these 12 questions in the local language (Kannada) by the investigators the following morning before breakfast. The volunteer’s were asked to tick-mark on the predefined scale in the particular box, rating each question as: 1=strongly disagree; 2=disagree; 3=neutral; 4=agree; 5=strongly agree.

The POMS questionnaire, which was used to evaluate the alcohol-induced hangover state in this study included the following 12 questions to evaluate the concerned parameter: (a) "Tension"-Do you feel emotionally stretched out or as being under some kind of unusual nervous strain or pressure? (b) "Anxiety"-Do you have a feeling of being generalized and vague, uneasy or apprehensive? (c) "Depression"-Do you have a feeling of sadness or helplessness? (d) "Depression"-Do you have a feeling of nonspecific or generalized aggressive-

### Table 1: BMI of the "PartySmart" and "Compared formulation" groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
</tr>
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<tbody>
<tr>
<td>Mean ± SEM</td>
<td>24.1 ± 0.4464</td>
<td>25.41 ± 1.126</td>
</tr>
<tr>
<td>p value summary</td>
<td>t=1.080, R²=0.06081, p=0.2946; NS</td>
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**Figure 1: Profile of trial (R=randomization)**
Table 2: Predefined amount of alcohol (ml) consumed to induce hangover in the “PartySmart” and “Compared formulation” groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
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<tbody>
<tr>
<td>Mean ± SEM</td>
<td>158 ± 10.52</td>
<td>153 ± 10.44</td>
</tr>
</tbody>
</table>

*p value summary*  
$t=0.3374$, $R^2=0.006283$, $p=0.7398$; NS

Table 3: Actual amount of alcohol consumed (ml) by the “PartySmart” and “Compared formulation” groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
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</thead>
<tbody>
<tr>
<td>Mean ± SEM</td>
<td>186 ± 4.129</td>
<td>175.5 ± 3.283</td>
</tr>
</tbody>
</table>

*p value summary*  
$t=1.990$, $R^2=0.09441$, $p=0.0538$; NS

Table 4: Severity of hangover in the “PartySmart” and “Compared formulation” groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
</tr>
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<tbody>
<tr>
<td>Mean ± SEM</td>
<td>0.6 ± 0.1338</td>
<td>2.4 ± 0.2449</td>
</tr>
</tbody>
</table>

*p value summary*  
$t=6.449$, $R^2=0.5226$, $p<0.0001$; HS

Figure 2: Severity of mean hangover score in the PartySmart and “Compared formulation” groups

* $t=6.449$, $R^2=0.5226$, $p<0.0001$; HS

Clinical papers

Due to inability to understand or comprehend these questions? Each volunteer also indicated the severity of each alcohol-induced hangover symptom, on a predefined symptom score scale, and on another visual analogue score scale. The physical parameters for the evaluation of hangover included (a) "Headache", (b) "Facial and dermal flushing", (c) "Nausea", (d) "Burning sensation in the stomach", (e) "Tachycardia", (f) "Body ache", (g) "Burning sensation in the eyes", (h) "Drowsiness" and, (i) "Overall feeling" (euphoric / dysphoric and fresh / lousy). The volunteers were asked to tick-mark these predefined score scales rating each symptom as: 1=nil; 2=negligible; 3=mild; 4=moderate; 5=severe. The final hangover scores were derived after averaging the scores of POMS, symptom score scale, and visual analogue score scale.

Crossover of volunteers

As per the crossover design, participants received the opposite treatment after a week of washout period, following the same procedure, and all the participants consumed the same type and amount of alcoholic drink during the second study day.

Primary and secondary endpoints

The predefined primary endpoints were the difference in final hangover score, and alcohol and acetaldehyde levels in blood and urine. The predefined secondary endpoints were reduced incidence of adverse effects, and the overall compliance to the drug under investigation.

Intercurrent illness and concomitant medication

The investigators recorded any information about intercurrent illness, therapeutic interventions and concomitant medication. Antacid or any other drug given for symptomatic relief from acute alcohol induced gastritis was allowed concomitantly with the study medication.
Adverse events
All the adverse events reported by the subjects or observed by the investigators were recorded with information about severity, date of onset, duration and action taken regarding the study drugs. Relation of adverse events to study medication was predefined as “Unrelated”, “Possible”, and “Probable”.

Analysis of data
The data analyst was blind to the treatment allocation and the analysis was performed according to intent-to-treat principles. For each variable, participants were grouped according to the sequence of intervention (“PartySmart” then the “Compared formulation”, or “the Compared formulation” then “PartySmart”). The “Independent Sample’s Unpaired ‘t’ Test” was used to compare both the groups for baseline parameters, predefined amount of alcohol to induce hangover, actual alcohol consumption and for the changes in various biochemical parameters. A two-sided p value of less than 0.001 was considered significant, and a power of 80% was considered for this two-treatment crossover trial.

RESULTS
There were 10 volunteers in the each group (“PartySmart group” and “Compared formulation group”), on both days of the study (Figure 1). There was no significant difference in the age and BMI in both the groups (p=0.2946) (Table 1). Similarly, there was no significant difference in the mean predefined amount of alcohol consumed to experience the hangover (p=0.7398) (Table 2), and also in the mean amount of alcohol actually consumed by the volunteers (p=0.0538) (Table 3) from the both groups during the study period.

There was a highly significant difference in the mean final hangover score, which was significantly higher in the Compared formulation group, as compared to the PartySmart group.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SEM</td>
<td>32.36 ± 3.076</td>
<td>32.83 ± 3.553</td>
</tr>
<tr>
<td>p value summary</td>
<td>t=0.09970, R²=0.0002615, p=0.9211; NS</td>
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</table>

Table 5: Blood alcohol levels (mg/dl) after 2 hours in the “PartySmart” and “Compared formulation” groups

<table>
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<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
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<tbody>
<tr>
<td>Mean ± SEM</td>
<td>0.96 ± 0.09263</td>
<td>3.157 ± 0.3013</td>
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<tr>
<td>p value summary</td>
<td>t=6.969, R²=0.561, p&lt;0.0001; HS</td>
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Table 6: Blood alcohol levels (mg/dl) after 10 hours in the “PartySmart” and “Compared formulation” groups

Figure 3: Blood alcohol levels after 2 hours in the “PartySmart” and “Compared formulation” groups

Figure 4: Blood alcohol levels after 10 hours in the “PartySmart” and “Compared formulation” groups
There was no significant difference in both the groups, in the mean blood alcohol levels after 2 hours (\(p=0.9211\)) (Table 5 and Figure 3), but there was a highly significant difference in the mean blood alcohol levels after 10 hours (\(p<0.0001\)) (Table 6 and Figure 4). There was a highly significant difference in both the groups, in the mean blood acetaldehyde levels after 2 hours (\(p<0.0001\)) (Table 7 and Figure 5) and 10 hours (\(p<0.0001\)) (Table 8 and Figure 6).

There was no significant difference in both the groups, in the mean urinary alcohol levels after 2 hours (\(p=0.725\)) (Table 9 and Figure 7) and there was a highly significant difference in the mean urinary alcohol levels after 10 hours (\(p<0.0001\)) (Table 10 and Figure 8). There was no significant difference in both the groups, in the mean urinary acetaldehyde levels after 2 hours (\(p=0.3328\)) (Table 11 and Figure 9) and there was a highly significant difference in the same after 10 hours (\(p<0.0001\)) (Table 12 and Figure 10).

There were no clinically significant adverse reactions, either observed by investigators or reported by the volunteers, in the both groups and overall compliance was good.

**DISCUSSION**

A hangover is characterized by unpleasant physical and mental symptoms that occur after a bout of heavy alcohol drinking. Physical symptoms of a hangover include fatigue, headache, increased sensitivity to light and sound, redness of the eyes, muscle aches, thirst, increased systolic blood pressure, tachycardia, tremors, and sweating. Mental symptoms include dizziness, vertigo, cognitive and mood disturbances (depression, anxiety, and irritability). Typically, a hangover begins within several hours after the cessation of drinking, and symptoms may continue for up to 24 hours.
thereafter. A hangover impairs task performance, and increases the risk of injury.\textsuperscript{10,11}

Generally, the greater the amount and duration of alcohol consumption, the more prevalent is the hangover, although some people report experiencing a hangover after drinking low levels of alcohol. In a study, researchers found an association between increased weekly alcohol consumption and the frequency of hangover.\textsuperscript{12} Similarly, in another study, 50 percent of the subjects who drank 2 or more drinks/day reported hangovers, more than the subjects who consumed lower levels of alcohol.\textsuperscript{13}

Hangover symptoms have been attributed to several causes, including the direct physiological effects of alcohol, the effects of the removal of alcohol, the physiological effects of compounds produced as a result of metabolism, and nonalcoholic factors (the toxic effects of other biologically active chemicals in the beverage, behaviors associated with the alcohol-drinking bout, and certain personal characteristics).\textsuperscript{2}

Alcohol causes diuresis, and promotes urine production by inhibiting the release of antidiuretic hormone (ADH/vasopressin), which prevents the kidneys from reabsorbing water. The symptoms of mild-to-moderate dehydration are commonly observed during a hangover.\textsuperscript{15}

Alcohol irritates the gastrointestinal tract, causing gastritis, delayed gastric emptying, increased acid, pancreatic and intestinal secretions, increased accumulation of triglycerides and free fatty acids in liver, and any or all of these factors may result in upper abdominal pain, nausea, and vomiting experienced during a hangover.\textsuperscript{16} Several alterations in the metabolic processes in response to alcohol can lead to hypoglycemia.\textsuperscript{17} Prolonged alcohol consumption, coupled with poor

### Table 9: Urine alcohol levels (mg/dl) after 2 hours in the “PartySmart” and “Compared formulation” groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
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</thead>
<tbody>
<tr>
<td>Mean ± SEM</td>
<td>43.82 ± 4.687</td>
<td>46.25 ± 5.001</td>
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<tr>
<td>p value summary</td>
<td>$t=0.3544$, $R^2=0.003294$, $p=0.725$; NS</td>
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### Table 10: Urine alcohol levels (mg/dl) after 10 hours in the “PartySmart” and “Compared formulation” groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SEM</td>
<td>11.02 ± 1.547</td>
<td>38.77 ± 4.41</td>
</tr>
<tr>
<td>p value summary</td>
<td>$t=5.937$, $R^2=0.4812$, $p&lt;0.0001$; HS</td>
<td></td>
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</tbody>
</table>
nutritional intake decreases glucose production and exhausts the hepatic glucose reserves (in the form of glycogen), thereby leading to hypoglycemia, which contributes to hangover symptoms.2

Although alcohol has sedative effects, the fatigue experienced during a hangover results from alcohol’s disruptive effects on sleep. Alcohol-induced sleep is of shorter duration and poorer quality, because of rebound excitation, leading to insomnia.18 In addition, alcohol relaxes the throat muscles, resulting in increased snoring, and periodic sleep apnea. Alcohol disrupts the circadian rhythm of body temperature, nighttime secretion of growth hormone (GH), adrenocorticotropic hormone (ACTH), and cortisol.2,19

An alcohol intoxication results in vasodilatation, which induces headaches,20 and alcohol has effects on several neurotransmitters and hormones that are implicated in the pathogenesis of headaches.21 Several lines of evidence suggest that a hangover is a mild manifestation of the AW syndrome in non-alcohol dependent drinkers, as the signs and symptoms of hangover and mild AW overlap considerably. The revised Clinical Institute Withdrawal Assessment for Alcohol (CIWA-Ar) scale (an instrument widely used to assess the severity of a withdrawal episode in alcohol-dependent patients), measures withdrawal-associated items, which are also commonly present during a hangover.22 Alcohol readministration alleviates the unpleasantness of both AW syndrome and hangover, and suggests that these experiences share a common process.2

Alcohol is removed from the bloodstream by a combination of metabolism, excretion, and evaporation. Alcohol metabolism is mainly by the group of 6 enzymes, collectively called ADHs, which convert the alcohol into acetaldehyde, and subsequently, another enzyme ALDH converts the acetaldehyde into non-toxic acetyl-CoA. Typical doses of alcohol actually saturate these enzymes’ capacity, so that alcohol is removed from the bloodstream at an approximately constant rate. This rate varies considerably between individuals, and persons below the age of 25, women, persons of certain ethnicities, and persons with liver disease, process alcohol more slowly. Many East Asians have impaired ALDH; this causes acetaldehyde levels to peak higher, producing more severe hangovers. Rate of detoxification of alcohol can also be slowed by certain drugs, which interfere with the action of ADHs.2

Most alcoholic beverages contain smaller amounts of other biologically active compounds (including other alcohols), and these compounds, known as congeners, contribute to the taste, smell, and appearance of alcoholic beverages. Research has shown that beverages composed of more pure ethanol (gin or vodka), induce fewer hangover effects than do beverages containing a large number of congeners (whiskey, brandy, or red wine).23,24

Some evidence exists that increased hangover symptoms occur more often in people possessing certain personality traits (neuroticism, anger, and defensiveness); and negative life events and feelings of guilt about drinking are associated with hangovers.25 Earleywine et al.,26,27 reported greater hangover symptoms in people who have a higher personality risk for the development of alcoholism.28 These studies suggest that people who have personality risk for alcoholism, experience more withdrawal and hangover symptoms. Research has shown that a history of alcoholism in a person’s family is associated with a greater risk for developing alcoholism.29,30

Many treatments are described to

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<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
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</thead>
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<tr>
<td>Mean ± SEM</td>
<td>25.77 ± 3.15</td>
<td>22.05 ± 2.118</td>
</tr>
<tr>
<td>p value summary</td>
<td>t=0.9810, R²=0.0247, p=0.3328; NS</td>
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Table 11: Urine acetaldehyde levels (µg/ml) after 2 hours in the “PartySmart” and “Compared formulation” groups
Table 12: Urine acetaldehyde levels (µg/ml) after 10 hours in the "PartySmart" and "Compared formulation" groups

<table>
<thead>
<tr>
<th>Parameters</th>
<th>PartySmart group</th>
<th>Compared formulation group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean ± SEM</td>
<td>49.13 ± 2.952</td>
<td>24.46 ± 3.109</td>
</tr>
<tr>
<td>p value summary</td>
<td>t=5.755, R²=0.4657, p&lt;0.0001; HS</td>
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![Figure 10: Urine acetaldehyde levels after 10 hours in the "PartySmart" and "Compared formulation" groups](image)

CONCLUSION

Despite its long history, little is known about the physiology of hangover. There are some formulations, which are being promoted as a cure for alcohol-induced hangover; but the claims made by these formulations have not been substantiated with evidence generated from controlled clinical trials. "PartySmart" is a polyherbal formulation recommended for the prevention of alcohol-induced hangover, and this study was planned to evaluate the efficacy and safety of "PartySmart" in the prevention of the alcohol-induced hangover symptoms, with one of Compared formulations, which is promoted as a cure for alcohol-induced hangover.

This study observed a highly significant difference in the mean final hangover score (which was higher in the Compared formulation group, as compared to the PartySmart group), the mean blood alcohol levels after 10 hours, the mean blood acetaldehyde levels after 2 and 10 hours, mean urinary alcohol levels after 10 hours, and the mean urinary acetaldehyde levels after 10 hours. There were no clinically significant adverse reactions, and overall compliance was good. These beneficial effects of "PartySmart" might be due to the synergistic actions of the ingredients of PartySmart.

In previous studies, also, the administration of "PartySmart" before the consumption of alcohol caused higher blood alcohol (possibly by inhibiting the presystemic metabolism of alcohol) and blood acetaldehyde levels after 2 hours, and the rapid lowering of acetaldehyde concentration in the blood was reflected in a significantly higher excretion of acetaldehyde in the urine over a 10-hour period. These results suggest that "PartySmart" prevents the binding of acetaldehyde to cell proteins, causing a higher initial blood level, and subsequent rapid elimination. Lower levels of alcohol and acetaldehyde in the blood at 10 hours were reflected in the decreased symptom scores, and the change in the final hangover score. These observations are indicative of a reduced hangover after pretreatment with "PartySmart". In the "Compared formulation" group, increase in the POMS scores for mood states indicated that the alcohol challenge had the anticipated effect.

Therefore, it may be concluded that "PartySmart" is effective and safe...
in the prevention of the alcohol-induced hangover symptoms, and is more effective than the "Compared formulation".

REFERENCES
1. Lisa La, Tourette-Pershan 2004 www.raggededge.btinternet.co.uk