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An intervention based on Well-Being Therapy to prevent alcohol use and other unhealthy lifestyle behaviors among students: a three-arm cluster randomized controlled trial

Luana Fantini^a, Sara Gostoli^{a*}, Michael G. Artin^b, Chiara Rafanelli^a

^a *Department of Psychology “Renzo Canestrari”, University of Bologna, Bologna, Italy*

^b *Vagelos College of Physicians and Surgeons, Columbia University, New York, NY, United States*

*Corresponding author:

Sara Gostoli, Department of Psychology “Renzo Canestrari”, University of Bologna, Viale Berti Pichat 5, 40127 Bologna (Italy). E-mail: sara.gostoli2@unibo.it

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ABSTRACT

Unhealthy lifestyle, such as alcohol use, and negative health outcomes have been associated with impairments in psychological well-being. The primary objective of the study was to test the efficacy of an intervention based on Well-Being Therapy to prevent or stem alcohol use, binge drinking, and other unhealthy lifestyle among Italian adolescents in school settings. A three-arm cluster randomized controlled trial including three test periods (baseline, post-test, six-month follow-up) was implemented. Seven classes (144 students) were randomly assigned to receive well-being intervention (WBI), lifestyle intervention (LI), or no intervention (NI). Primary outcomes were alcohol use (AUDIT-C), binge drinking and other unhealthy lifestyle behaviors (i.e., unhealthy diet, physical inactivity, tobacco and cannabis smoke, poor sleep and Internet addiction). Linear mixed models and mixed-effects logistic regression were used to test the efficacy of WBI in comparison with LI and NI. At six-month follow-up, AUDIT-C total score increased more in NI in comparison with WBI ($p= 0.044$) and LI ($p= 0.016$), whereas the odds to be classified as at-risk drinker were lower in WBI ($p= 0.038$) and LI ($p= 0.002$), than NI. Only WBI showed a protective effect for cannabis use at post-test in comparison with NI ($p= 0.003$) and LI ($p= 0.014$). Sleep hours at night decreased more in NI than LI ($p= 0.027$) at six months. Internet addiction decreased more in WBI ($p= 0.002$) and LI ($p= 0.005$) at post-test in comparison with NI. Although both interventions showed a positive impact on adolescent lifestyle, the positive effect of WBI on cannabis use underlines how this approach might be promising to stem adolescents' substance use.

Keywords: adolescence, alcohol, binge drinking, lifestyle, psychological well-being, well-being therapy.

Introduction

Unhealthy lifestyle, such as alcohol use, tends to increase during adolescence (Schuler et al., 2015; GBD 2019 Risk Factors Collaborators, 2020; Marques et al., 2020). Behaviors acquired during adolescence can be carried over into adulthood (Akasaki et al., 2019; Marques et al., 2020). Moreover, unhealthy behaviors, often comorbid, also raise lifetime prevalence of mental diseases (Firth et al., 2020). Therefore, an effective intervention that might prevent or stem an increase in unhealthy lifestyle at an early age would have crucial positive impact for both physical and mental health.

Both adolescents and adults who adopt healthy lifestyle behaviors and make protective health decisions have shown balance in psychological well-being (PWB) areas (Gostoli et al., 2021a; Gostoli et al., 2021b; Zhu et al., 2022). According to the eudaimonic perspective, PWB represents the complete flourishing and achievement of one's potential (Ryan & Deci, 2001). Ryff (Ryff, 1989, 2014), based on Jahoda's work (Jahoda, 1958), developed six theory-based indicators (environmental mastery, personal growth, purpose in life, autonomy, self-acceptance, positive relationships). Impairments in these dimensions have been associated with unhealthy lifestyle and negative health outcomes among clinical adult populations (Gostoli et al., 2021b; Zhu et al., 2022) and non-clinical samples of adolescents (Gostoli et al., 2021a; Rafanelli et al., 2016). Among Italian young adolescents, unbalanced levels in PWB, specifically lower purpose in life and stronger positive relationships, were associated with binge drinking (BD) (Gostoli et al., 2021a). Therefore, balanced levels within PWB dimensions might protect against the increase in alcohol use, BD, and unhealthy lifestyle during adolescence (Marques et al., 2020).

Among the interventions developed to achieve balanced PWB, Well-Being Therapy (WBT; Fava, 2016) showed beneficial effects, in terms of modulating PWB dimensions, promoting adaption to new life circumstances, reducing clinical and sub-threshold psychological distress, in both clinical and non-clinical settings (Fava et al., 2005; Moenizadeh & Zarif, 2017; Ruini et al.,

2009, 2015; Tomba et al., 2010; Xu et al., 2019). However, it has never been applied to prevent alcohol use, BD, or other unhealthy lifestyle behaviors among young adolescents. Moreover, other kinds of primary prevention interventions for adolescents, such as family-based programs (focusing on development of parenting skills), universal school-based prevention programs (involving education, development of social skills like peer resistance, generic healthy school/community initiatives), brief school-based interventions (based on giving information/advice, increasing motivation against substances use, teaching behavior change skills), universal multicomponent prevention programs (delivered in multiple settings, typically combining school and parenting intervention, but also at the community level), and mentoring programs, have shown inconclusive findings (Ryan et al., 2019). To bridge this gap, the present study aimed to test a WBT-based intervention (Well-Being Intervention, WBI) in school setting to prevent/stem alcohol use, BD, and other unhealthy lifestyle behaviors, such as diet, physical inactivity, tobacco and cannabis smoke, poor sleep and Internet addiction (first outcome). Considering that WBI involved strategies to improve problem-solving abilities, a positive effect on these skills was expected (second outcome). In addition, WBI was hypothesized to reduce psychological distress (third outcome), in line with previous findings (Ruini et al., 2009; Tomba et al., 2010). Since different effects were observed when comparing an intervention with another active intervention or inactive group (Carr et al., 2021), WBI was compared with both an educational program on healthy lifestyle (Lifestyle Intervention, LI) and no intervention (NI).

Methods

Participants

Students were enrolled if they: a) attended randomly selected schools; b) were in the first year of high school; c) had informed consent signed by parents or guardians; d) gave their informed assent

for participation in the study. Final recruitment resulted in 144 students (WBI=59; LI=41; NI=44), with 64.1% females and a median age of 14 (IQR=0).

Design

This was a three-arm, school-based, cluster RCT including three test periods (pre-test, post-test, and six-month). First-year high school students were enrolled from December 2018 to January 2019 in Ferrara (northeastern Italy). Two schools were randomly selected from all high schools in Ferrara with a random number generator and invited through publicly available contact information. After schools provided permission, all the first-year classes (N=7) were randomized to receive either WBI (N=3), LI (N=2) or no intervention (N=2). Students' anonymity was guaranteed at each assessment point by requesting them to self-attribute an alphanumerical code, which then they were asked to write down and remember during follow-up evaluations. Just in case participants would not recall the code at follow-ups, the questionnaire included specific ad-hoc items (i.e., "mother's date of birth" and "best childhood friend's name") that allowed the researchers to link the questionnaires fulfilled by the same participant. All eligible students underwent a first assessment at baseline (December 2018-January 2019), six two-hour meetings if in the WBI or LI group, a second assessment at the end of the sessions (March-April 2019), and a last assessment after six months (September-October 2019). *Figure 1* illustrates the flowchart of the study. Randomization, using a computerized random number generator, at the class level was performed. Classes were randomly assigned to WBI, LI, or NI. Parents, students, and teachers were blinded to group assignment (WBI and LI, but not NI), whereas the clinical psychologist was not blinded to experimental protocol.

The Ethics Committee of the Department of Psychology and the Bioethics Committee of the University of Bologna provided ethical approval for this cluster-randomized controlled trial (Prot. N. 0072226).

Interventions

Interventions (WBI and LI) in the classroom were conducted during school hours. They both consisted of six two-hour sessions held every 10-15 days and the participants were blinded to the intervention received. Sessions were performed by a clinical psychologist, previously trained in WBT. During the meetings, brainstorming, group discussions, games, role-playing, and videos were used for both intervention groups. The interventions are briefly described below. Full details are presented in the supplementary material.

WB intervention. WBI was based on WBT principles (Fava, 2016) and protocols previously implemented among Italian students (Ruini et al., 2009). According to WBT, specific elements of this intervention included: self-monitoring of episodes of well-being; identification of automatic thoughts leading to interruption of well-being; and discussion and modification of dysfunctional beliefs according to Ryff's PWB dimensions (1989). PWB dimensions were presented highlighting how a balanced level within the dimensions was adaptive. Specific activities were performed to achieve a more balanced level within the dimensions. During this intervention, students were trained to keep self-observation entries in a diary.

Lifestyle intervention. This intervention was based on lifestyle psychoeducation. All sessions aimed at improving knowledge about the benefits of implementing healthy behaviors (i.e., avoiding addiction, healthy diet, sport, and physical activity).

Assessment

Sociodemographic data, lifestyle, and psychological characteristics were collected at baseline, post-intervention, and six-month follow-up. All the questionnaires were self-administered.

Alcohol Use Disorder Identification Test-C (AUDIT-C) (Bush et al., 1998; Rumpf et al., 2013) was used to evaluate alcohol consumption. It consists of three items with answers on a 5-point Likert scale. Questions are scored from 0 to 4, which allows for a maximum sum score of 12. AUDIT-C has shown effectiveness in screening adolescents at-risk for alcohol use, BD, and alcohol abuse (Coulton et al., 2019; Liskola et al., 2018). A cut-off of ≥ 3 identifies at-risk drinking in

adolescents (Coulton et al., 2019; Deluca et al., 2020; Liskola et al., 2018). When students indicated drinking ≥ 5 alcoholic units in a single occasion at least once a month, they were classified as binge drinkers (ESPAD, 2015).

Items derived from the *Cannabis Experience Questionnaire* (Barkus et al., 2006; Di Forti et al., 2009) were adapted to be easily understandable by young adolescents, and included to assess different aspects related to cannabis consumption, such as lifetime and current use, age at first use, beliefs about cannabis use, motivations to use, and frequency.

Psychological Well-Being Scales (PWBS) (18 items) (Ryff & Singer, 1996; Sirigatti et al., 2013) were used to assess PWB dimensions, in line with Ryff's conceptualization (1989): autonomy, environmental mastery, personal growth, positive relations, purpose in life and self-acceptance. Answers were given on a 6-point Likert scale (from 1 = 'strongly disagree' to 6 = 'strongly agree'). The higher the scores, the higher the levels of PWB. Internal consistency among Italian youth population ranged from $\alpha = 0.55$ to $\alpha = 0.87$ (Casale et al., 2015; Gigantesco et al., 2011; Liga et al., 2020).

Problem Solving Inventory – Italian Adolescents (PSI-IT) (35 items) (Heppner, 1998; Nota et al., 2013) was used to measure individual perception of problem-solving abilities. PSI-IT measures: Problem Solving Engagement (PSE, tendency to engage or approach problems); Self-Assurance (SA, tendency to feel efficacious in solving problems); and Methodical Thinking (MT, ability to systematically think about problem resolution). Items can be answered on a 6-point Likert scale (from 1 = 'strongly agree' to 6 = 'strongly disagree'). Higher scores correspond to higher self-evaluated problem-solving abilities. Internal consistency estimates of the three factors (i.e., PSE, SA, MT) and the total score were 0.83, 0.77, 0.69 and 0.85, respectively (Nota et al., 2013).

Symptom Questionnaire (SQ) (92 items) (Benasi et al., 2020; Kellner, 1987) was used to evaluate 4 dimensions of subclinical psychological distress (i.e., anxiety, depression, somatization, and hostility-anger). Items have a dichotomous scale (Yes/No or True/False) and each dimension might range from 0 to 23. Higher scores indicate higher psychological distress. SQ showed

Cronbach α coefficients ranged from 0.74 (hostility scale) to 0.34 (somatization scale) (Vescovelli et al., 2014)

PsychoSocial Index (53 items) (Piolanti et al., 2016; Sonino & Fava, 1998) was employed to investigate the presence of stressful events and allostatic overload. Participants have to answer on a dichotomous scale (Yes/No) to some items and on a Likert scale to others (from 0 = ‘not at all’ to 3 = ‘a great deal’). The operationalization of allostatic overload is based on specific clinimetric criteria developed by Fava and his colleagues (Fava et al., 2010, 2017). Criterion A requires the presence of an identifiable stressor that must be judged as exceeding or taxing the individual’s coping skills. Criterion B requires the stressor to be associated with at least one manifestation among psychiatric or psychosomatic symptoms, impaired functioning, or compromised well-being. *PsychoSocial Index* showed intraclass correlation coefficients ranging from 0.94 to 0.80 (Sonino & Fava, 1998).

Statistical analyses

Baseline characteristics (i.e., sociodemographic, lifestyle, and psychological) for each treatment group were presented, with binary variables reported as percentages, and continuous variables as mean and SD for normally distributed variables or median and interquartile range for non-normally distributed variables (*Tables 1 and 2*). In order to prevent attrition bias (McCoy, 2017), outcomes were analyzed according to the intention-to-treat (ITT) principle using linear mixed models for continuous outcomes and generalized linear mixed models for binary outcomes. Since mixed models allow analysis of all available data with acceptable bias under a missing at random assumption, no imputation method was used for missing data. All models included fixed effects for treatment group, time (treated as categorical), and group-by-time interactions for the primary treatment effects and school, sex, and socioeconomic status as covariates for adjustment. Random effects were included to account for clustering at the student and class level using a random intercept. Cohen’s *d* was calculated to determine standardized effect sizes for changes over time

between and within each group (*Table 3*), using Cohen's conventions for magnitude (small= 0.2; moderate= 0.5; large \geq 0.8) (Cohen, 1992). Continuous results were reported as adjusted difference in change (*Table 4*) and binary results as adjusted odds ratio (AOR) (*Table 5*). The Akaike Information Criterion (AIC) (Akaike, 1974) and Bayesian Information Criterion (BIC) (Schwarz, 1978), were used to assess models fit (*Table 6*). Observed means for continuous outcomes were reported in supplementary material. All alpha levels were set at $p < 0.05$. Analyses were performed with R (version 4.1.1, The R Foundation for Statistical Computing, Vienna, Austria), using the packages *lme4* and *lmerTest* for fitting linear and generalized linear mixed models, *emmeans* for estimated marginal means and predictions.

Results

Description of the sample

Baseline characteristics of the sample are detailed in *Table 1* (i.e., sociodemographic and lifestyle characteristics) and *Table 2* (i.e., psychological variables).

Primary outcomes

Alcohol use and BD

Regarding the linear mixed model, the group-by-time interaction was statistically significant for the AUDIT-C total score for WBI ($p = 0.044$) and LI ($p = 0.016$) in comparison with NI from baseline to six-month follow-up. AUDIT-C total score increased less in WBI (B= -0.678; 95%CI -1.326, -0.028) and LI (B= -0.887; 95%CI -1.600, -0.180) in comparison with NI considering changes from baseline to six-month follow-up (*Table 4*).

Considering binary variables (i.e., BD, at-risk drinking), the main results from mixed-effects logistic regression are presented below and in *Table 5*, for a more detailed view. Odds to be classified as binge drinker for WBI in comparison with NI from baseline to post-test (OR= 0.589;

95%CI 0.013, 27.379) and from baseline to six-month follow-up (OR= 0.772; 95%CI 0.019, 31.838), were not statistically different. Odds to be classified as a binge drinker for LI in comparison with NI from baseline to post-test (OR= 0.390; 95%CI 0.008, 17.993) and from baseline to six-month follow-up (OR= 0.157; 95%CI 0.004, 6.660), were not statistically different. Odds to be classified as at-risk drinker in WBI (OR= 5.426; 95%CI 0.142, 207.009) and LI (OR= 1.433; 95%CI 0.030, 68.967) were not statistically different from NI at post-test in comparison with baseline. Otherwise, at six-month follow-up, both WBI (OR= 0.011; 95%CI 0.0002, 0.783; $p= 0.038$) and LI (OR= 0.0005; 95%CI 0.000, 0.059; $p= 0.002$) reduced the odds to be classified as an at-risk drinker in comparison with NI.

Lifestyle

Mixed-effects logistic regression for binary outcomes (i.e., tobacco smoking, e-cigarettes use, cannabis use, physical activity, sport, and healthy diet) did not show significant differences between groups, except for cannabis use (*Table 5*). Odds to use cannabis were less in WBI than LI (OR= 49086.467; 95%CI 8.644, 278731300; $p= 0.014$) and NI (OR= 0.000; 95%CI 0.000, 0.018; $p= 0.003$), from baseline to post-test.

Linear mixed models showed that sleep hours at night decreased more in NI than in LI (B= 0.670; 95%CI 0.087, 1.252; $p= 0.027$) from baseline to six-month follow-up (*Table 4*). Internet addiction scores decreased in WBI (B= -2.304; 95%CI -3.768, -0.842; $p= 0.002$) and LI (B= -2.270; 95%CI -3.828, -0.697; $p= 0.005$) from baseline to post-test in comparison with NI (*Table 4*).

Secondary outcomes

Problem-solving abilities

Linear mixed models did not show significant differences in problem-solving abilities, apart from the sub-dimension Methodical Thinking that increased more in WBI (B= 2.385; 95%CI 0.001, 4.774; $p= 0.053$) than in NI from baseline to six-month follow-up (*Table 4*).

Psychological distress

Regarding psychological distress, the linear mixed model did not show an effect of the interventions (i.e., WBI and LI) on anxiety, depression, somatization, and hostility (*Table 4*).

Mixed-effects logistic regression showed that the odds to be classified positive for allostatic overload was less in LI in comparison with NI from baseline to six-month follow-up (OR= 0.144; 95%CI 0.022, 0.919; $p= 0.040$), and with WBI from baseline to post-test (OR= 0.044; 95%CI 0.004, 0.528; $p= 0.014$) and to six-month follow-up (OR= 0.102; 95%CI 0.017, 0.614; $p= 0.013$) (*Table 5*). Summary of all models fit diagnostics are reported in *Table 6*. Both AIC and BIC indicate better model adequacy with small values.

Discussion

To the best of our knowledge, this is the first study that evaluates the possible benefits of an intervention based on WBT (Fava, 2016) in fostering the reduction or prevention of alcohol use and other unhealthy lifestyle behaviors in adolescence.

The hypotheses of this study were partially confirmed. WBI showed overall better results on lifestyle in comparison with a non-active group (NI). Moreover, WBI played a more positive effect on cannabis use compared with another intervention (LI). This is in line with Carr and colleagues' (2021) review. Regarding alcohol use, both the interventions (WBI and LI) showed a protective effect, in comparison with NI, on the total score of the AUDIT-C and on the odds to be classified as at-risk drinker. Considering that alcohol use during adolescence tends to increase (Schuler et al., 2015; GBD 2019 Risk Factors Collaborators, 2020), both interventions had a positive effect in comparison with the usual activities in class (NI). Limiting the rise of drinking among early-onset drinkers may help to delay the start of problem drinking in the long run with important public health implications. On the other hand, WBI and LI did not show an effect on BD. This could be explained

by the difficulty measuring the phenomenon (Lannoy et al., 2021). Indeed, Lannoy and colleagues (2021) concluded that the evaluation of BD should include subjective drunkenness together with quantitative measures (intensity and frequency of alcohol use). Another possible explanation for the lack of effect on BD is the longer amount of time necessary to see such a behavioral change in adolescents (Lammers et al., 2017; Velicer et al., 2013), which suggests the utility of providing longer-term assessments.

Regarding other psychoactive substances, improving PWB, rather than increasing health knowledge, showed potential for preventing the raise in cannabis use at this age, when autonomy from the family and influence from peers increase (Doumas et al., 2015; Laghi et al., 2012). Moreover, a tendency to risk is raised by an imbalance in the development of the brain areas responsible for gratification and those for rational decision-making and control (Balocchini et al., 2013; Blakemore, 2008). Since cannabis use grows from early to late adolescence (Chen & Kandel, 1995; Hawke et al., 2020), the positive impact of WBI on substance use represents a crucial finding in relation to several issues resulting from cannabis use, which could occur across the life span, such as cannabis dependence syndrome, schizophreniform psychosis, anxiety and depressive disorders, acute and perhaps chronic cognitive impairments, structural and functional changes in brain pathways implicated in reward, learning and addiction (Hall et al, 2019).

Physical and sport activity, fruits and vegetable consumption, and healthy diet showed a decrease in the three groups over time, in line with the tendency for adolescents to have a less healthy lifestyle from early to late adolescence (Marques et al., 2020). In this case, neither WBI nor LI had a protective effect. On the other hand, both the interventions showed a protective role on internet addiction and only LI on sleep at night. Previous findings showed that internet use and sleep problems were associated among adolescents (Cabr -Riera et al., 2019; Ekinci et al., 2014; Evers et al., 2020). The decrease in the scoring of internet addiction after the interventions (WBI and LI) possibly explain the positive long-term effect on sleep, which decreased in the group without intervention and remained almost unchanged in the groups undergoing one of the two

interventions. Future research should test this hypothesis experimentally. Based on sleep quantity, the mean sleep hours in this sample were lower than those recommended (8 to 10 hours per night) (Hirshkowitz et al., 2015). In the future, it will be important to measure sleep quality, which is a better predictor of optimal sleep than sleep quantity (Hirshkowitz et al., 2015; Olashore et al., 2020).

In line with our hypothesis, WBI, but not LI, increased the ability to solve problems, both systematically and methodically. Improving problem-solving abilities may lead to dealing with negative emotions and stress in a more adaptive way than to use alcohol or engage in unhealthy behaviors (Dreer et al., 2004; Jaffee & D’Zurilla, 2003; Williams & Kleinfilter, 1989). Longer-term follow-up would be necessary to see if the improvement of problem-solving could reduce unhealthy behaviors.

Concerning psychological distress, WBI was not effective in decreasing anxiety, depression, somatization, and hostility symptoms in contrast to what had been found in previous studies (Ruini et al., 2009; Tomba et al., 2010). A possible explanation for these incongruent findings could depend on the fact that in the mentioned studies, participants joined the trial on a voluntary basis, whereas in the present investigation schools were randomly selected and classes designated by the principal after a consultation with the teaching staff. Therefore, the initial motivation of the participants could have been different. Finally, LI, but not WBI, had a positive effect on allostatic overload, showing that students who followed this intervention had a lower chance to report the negative consequences of stressful events than their peers.

Considering that most effects appeared after six months post-treatment, it could be hypothesized that changes in lifestyle, problem-solving abilities, and psychological distress required a certain amount of time. Therefore, it would be desirable to test the effects of these interventions over the long term to see whether the changes recorded at six-month follow-up are maintained over time or if new improvements appear.

Some limitations should be considered. First, the use of self-report questionnaires could lead to potential biases due to social desirability, underestimation of alcohol consumption, and recall errors (Brener et al., 2003). Nevertheless, in adolescents, self-report measures seem to show good validity and reliability (Lintonen et al., 2004), especially when anonymously administered (Brener et al., 2003). Second, the small sample was not representative of Italian or international high school students. Further research should include larger samples, representative of other geographical areas. Third, students reported a lack of motivation in fulfilling their well-being diary, which is one of the pillar components of the WBT (Fava, 2016). Future research should improve their motivation making it more appealing or implement web-based or smartphone application with reminders, which might engage participants and encourage introspection (van Agteren et al., 2021). Fourth, given the specific design of the study (i.e., classrooms from the same school received different interventions), a possible contamination among interventions, due to social interactions between students from different classes, cannot be excluded. Finally, further limitations concern the facts that highly skewed data were summarized using symmetrical measures and that some of the ORs were extremely large or extremely small, and thus they should be interpreted with caution.

This study also has several strengths, such as cluster RCT design, intention to treat analysis, active control group involvement, and theory-based intervention (Fava, 2016) to prevent unhealthy lifestyle behaviors in adolescents. Finally, since the intervention can be administered in the classroom to all the students, it is conceivable that schools could easily apply it without selecting participants according to specific characteristics, such as personality (Lammers et al., 2017).

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Table 1. Baseline sociodemographic and lifestyle characteristics of the students by study group.

	WBI	LI	NI
	(N=59)	(N=41)	(N=44)
	Median(IQR)	Median(IQR)	Median(IQR)
Age	14(0)	14(1)	14(0)
	Mean±SD	Mean±SD	Mean±SD
GPA	7.24±0.94	6.94±0.57	6.81±0.73
Sleep at night (hours)	7.25±1.23	7.14±1.28	6.71±1.24
Internet addiction (from 0 to 24)	7.77±4.31	7.22±4.12	7.93±4.1
	N(%)	N(%)	N(%)
Sex			
<i>Male</i>	22(37.9)	15(37.5)	14(31.8)
<i>Female</i>	36(62.1)	25(62.5)	30(68.2)
School			
<i>High school</i>	44(74.6)	23(56.1)	44(100)
<i>Technical/Professional</i>	15(25.4)	18(43.9)	0(0)
Socioeconomic status			
<i>High</i>	4(7.0)	4(10.0)	5(11.6)
<i>Middle</i>	50(87.7)	35(87.5)	33(76.7)
<i>Low</i>	3(5.3)	1(2.5)	5(11.6)

Immigration				
	<i>First-generation</i>	2(4.3)	2(6.5)	1(3.1)
	<i>Second-generation</i>	4(8.7)	4(12.9)	6(18.8)
Physical activity		30(53.6)	19(48.7)	22(52.4)
Sport activity		35(59.3)	28(68.3)	25(56.8)
Fruits and vegetables consumption		40(70.2)	21(51.2)	30(68.2)
Healthy diet at home		37(64.9)	24(61.5)	26(65)
Alcohol use		45(76.3)	28(68.3)	27(61.4)
Binge Drinking		5(8.5)	5(12.5)	3(6.8)
At-risk drinkers		10(17.2)	10(25.6)	7(16.7)
Caffeine		52(88.1)	30(73.2)	32(74.4)
Tobacco smoking		12(20.3)	12(29.3)	8(18.2)
E-cigarettes use		9(15.5)	4(9.8)	4(9.1)
Cannabis smoking		9(15.3)	7(17.1)	5(11.4)
Use of other drugs		2(3.4)	2(4.9)	1(2.3)

Abbreviations: WBI Well-Being Intervention; LI Lifestyle Intervention; NI No Intervention; GPA Grade Point Average

Table 2. Baseline psychological characteristics of the students according to the study group.

	WBI	LI	NI
	(N=59)	(N=41)	(N=44)
	N(%)	N(%)	N(%)
Allostatic overload	10(17.9)	10(27)	10(25)
	Mean±SD	Mean±SD	Mean±SD
<i>Symptom Questionnaire</i>			
Anxiety	7.21±5.14	7.58±5.27	9.55±5.58
Depression	5.62±4.66	6.64±5.79	9.00±6.76
Somatization	8.33±5.19	7.22±5.49	10.43±6.93
Hostility	6.92±5.64	6.95±5.98	8.64±5.71
<i>Psychosocial Index</i>			
Stressful events	3.00±2.33	3.64±2.42	4.64±3.06
Quality of life (from 0 to 4)	2.88±0.87	2.55±0.85	2.37±1.17
<i>Problem-Solving Inventory</i>			
Problem-Solving Engagement	54.60±11.43	52.09±10.71	56.16±12.03
Self-Assurance	28.92±8.30	30.66±6.69	29.42±7.21
Methodical Thinking	14.45±4.42	14.63±4.87	16.23±4.94
Total score	98.54±17.53	96.31±18.36	101.81±18.17

<i>Psychological Well-Being Scales</i>			
Autonomy	13.19±3.59	12.97±2.97	13.12±3.47
Environmental mastery	11.98±3.46	12.00±2.91	11.95±3.96
Personal growth	14.90±2.93	15.03±2.29	15.70±2.28
Positive relations	12.88±3.49	13.59±3.13	12.56±3.02
Purpose in life	11.28±2.54	11.87±3.01	10.98±3.58
Self-acceptance	11.69±3.34	11.73±2.99	10.65±3.85
Total score	75.78±12.20	77.11±8.02	74.95±12.22

Abbreviations: WBI Well-Being Intervention; LI Lifestyle Intervention; NI No Intervention

Table 3. Effect sizes calculated as Cohen's d

Outcomes	WBI (59)		LI (41)	
	Post-test	6-month follow-up	Post-test	6-month follow-up
AUDIT-total score	0.015	-0.421	-0.086	-0.510
Sleep	0.116	0.458	0.288	0.632
Internet Addiction	-0.482	-0.209	-0.545	-0.171
Problem-Solving Inventory				
<i>Problem-Solving Engagement</i>	-0.014	-0.014	0.057	0.006
<i>Self-Assurance</i>	-0.153	0.240	-0.148	0.290
<i>Methodical Thinking</i>	0.142	0.492	0.002	0.522
<i>Total score</i>	-0.087	0.209	0.036	0.294
Symptom Questionnaire				
<i>Anxiety</i>	0.113	-0.323	0.163	-0.399
<i>Depression</i>	-0.125	-0.429	-0.216	-0.474
<i>Somatization</i>	-0.008	-0.092	-0.030	-0.263
<i>Hostility</i>	0.046	-0.177	0.137	-0.182

Abbreviations: WBI Well-Being Intervention; LI Lifestyle Intervention

Table 4. Changes in primary and secondary continuous outcomes for WBI, LI, and NI groups.

Outcome ^a	Baseline, EMM (SE)	Post-test, EMM (SE)	6-months, EMM (SE)	Time ^b <i>p</i>	Time ^c <i>p</i>	Adjusted difference in change, Mean (95% CI) ^d	Group- by- time ^d , <i>p</i>	Adjusted difference in change, Mean (95% CI) ^e	Group- by- time ^e , <i>p</i>	Adjusted difference in change, Mean (95% CI) ^f	Group- by- time ^f , <i>p</i>	Adjusted difference in change, Mean (95% CI) ^g	Group- by- time ^g , <i>p</i>
<i>Lifestyle</i>													
AUDIT-C_total score													
WBI	1.06 (0.41)	1.47 (0.42)	1.69 (0.42)	0.143	0.010	0.118 (-0.526, 0.763)	0.722	-0.678 (-1.326, - 0.028)	0.044	0.463 (-0.176, 1.107)	0.163	0.209 (-0.439, 0.865)	0.534
LI	1.45 (0.44)	1.40 (0.45)	1.87 (0.46)	0.977	0.238	-0.345 (-1.034, 0.340)	0.331	-0.887 (-1.600, - 0.180)	0.016	-	-	-	-
NI	0.87 (0.46)	1.17 (0.47)	2.18 (0.47)	0.476	<0.001	-	-	-	-	-	-	-	-
Sleep													
WBI	7.23 (0.24)	7.27 (0.26)	6.72 (0.25)	0.963	0.011	0.302 (-0.231, 0.827)	0.268	0.402 (-0.129, 0.928)	0.141	0.054 (-0.477, 0.583)	0.842	-0.267 (-0.810, 0.271)	0.338
LI	7.12 (0.26)	7.11 (0.27)	6.88 (0.27)	0.999	0.506	0.247 (-0.321, 0.811)	0.397	0.670 (0.087, 1.252)	0.027	-	-	-	-
NI	6.81 (0.26)	6.56 (0.28)	5.90 (0.28)	0.431	<0.001	-	-	-	-	-	-	-	-
Internet Addiction													
WBI	7.17 (0.77)	6.42 (0.80)	7.35 (0.80)	0.272	0.930	-2.304 (-3.768, - 0.842)	0.002	-0.869 (-2.329, 0.584)	0.248	-0.034 (-1.484, 1.400)	0.963	-0.511 (-1.985, 0.966)	0.502
LI	6.94 (0.83)	6.22 (0.84)	7.62 (0.86)	0.413	0.478	-2.270 (-3.828, - 0.697)	0.005	-0.358 (-1.966, 1.241)	0.665	-	-	-	-
NI	6.97 (0.84)	8.52 (0.88)	8.01 (0.88)	0.021	0.170	-	-	-	-	-	-	-	-
<i>Problem-Solving Inventory</i>													

Problem-Solving Engagement													
WBI	53.1 (2.20)	52.6 (2.30)	54.1 (2.26)	0.964	0.870	-0.129 (-5.797, 5.537)	0.965	0.205 (-5.485, 5.925)	0.945	-2.038 (-7.946, 3.879)	0.505	-1.332 (-7.231, 4.540)	0.662
LI	51.7 (2.34)	53.2 (2.41)	54.0 (2.37)	0.786	0.577	1.909 (-4.191, 7.998)	0.544	1.536 (-4.612, 7.743)	0.630	-	-	-	-
NI	55.5 (2.24)	55.1 (2.42)	56.3 (2.46)	0.982	0.932	-	-	-	-	-	-	-	-
Self-Assurance													
WBI	28.7 (1.41)	30.9 (1.48)	30.7 (1.50)	0.254	0.330	-0.883 (-4.912, 3.095)	0.669	2.274 (-1.812, 6.354)	0.282	1.581 (-2.531, 5.709)	0.458	-0.007 (-4.215, 4.182)	0.997
LI	30.0 (1.56)	30.6 (1.57)	32.0 (1.60)	0.928	0.450	-2.464 (-6.843, 1.848)	0.272	2.281 (-2.142, 6.718)	0.319	-	-	-	-
NI	30.2 (1.49)	33.2 (1.63)	29.9 (1.66)	0.119	0.983	-	-	-	-	-	-	-	-
Methodical Thinking													
WBI	14.8 (0.83)	15.7 (0.87)	16.1 (0.88)	0.479	0.251	1.009 (-1.346, 3.336)	0.403	2.385 (0.001, 4.774)	0.053	1.454 (-0.918, 3.814)	0.234	0.297 (-2.114, 2.707)	0.811
LI	14.7 (0.91)	14.1 (0.95)	15.7 (0.96)	0.830	0.564	-0.445 (-2.989, 2.084)	0.734	2.088 (-0.502, 4.683)	0.120	-	-	-	-
NI	16.8 (0.89)	16.7 (0.97)	15.6 (0.99)	0.994	0.464	-	-	-	-	-	-	-	-
Total score													
WBI	97.7 (3.63)	99.4 (3.75)	101.4 (3.74)	0.866	0.507	-0.795 (-10.202, 8.521)	0.869	4.336 (-5.151, 13.895)	0.379	-0.848 (-10.736, 9.012)	0.868	-1.935 (-11.856, 7.948)	0.706
LI	96.1 (3.87)	98.6 (3.91)	101.7 (3.85)	0.785	0.304	0.053 (-10.052, 10.096)	0.992	6.271 (-3.854, 16.506)	0.234	-	-	-	-
NI	102.9 (3.65)	105.4 (3.95)	102.3 (4.01)	0.754	0.986	-	-	-	-	-	-	-	-
Symptom Questionnaire													

Anxiety													
WBI	8.25 (1.05)	8.72 (1.11)	10.36 (1.11)	0.877	0.071	0.824 (-1.981, 3.582)	0.566	-0.876 (-3.638, 1.880)	0.539	0.066 (-2.776, 2.895)	0.964	1.107 (-1.769, 3.986)	0.457
LI	8.98 (1.18)	9.38 (1.18)	9.98 (1.22)	0.932	0.660	0.758 (-2.258, 3.741)	0.625	-1.983 (-5.016, 1.042)	0.205	-	-	-	-
NI	9.50 (1.16)	9.14 (1.26)	12.48 (1.26)	0.940	0.015	-	-	-	-	-	-	-	-
Depression													
WBI	6.97 (1.41)	6.96 (1.43)	8.49 (1.44)	1.000	0.222	-1.007 (-3.653, 1.553)	0.454	-1.926 (-4.533, 0.663)	0.152	0.408 (-2.246, 3.082)	0.767	0.723 (-1.992, 3.413)	0.605
LI	8.08 (1.59)	7.67 (1.60)	8.88 (1.63)	0.917	0.728	-1.415 (-4.249, 1.312)	0.325	-2.648 (-5.435, 0.144)	0.067	-	-	-	-
NI	8.85 (1.71)	9.86 (1.77)	12.30 (1.77)	0.570	0.002	-	-	-	-	-	-	-	-
Somatization													
WBI	9.13 (1.16)	9.59 (1.25)	12.74 (1.22)	0.908	0.002	-0.794 (-3.925, 2.348)	0.624	0.119 (-2.987, 3.191)	0.941	-0.501 (-3.683, 2.684)	0.760	1.178 (-2.035, 4.394)	0.477
LI	8.40 (1.28)	9.36 (1.27)	10.82 (1.33)	0.719	0.141	-0.293 (-3.624, 3.046)	0.865	-1.061 (-4.454, 2.299)	0.543	-	-	-	-
NI	10.28 (1.23)	11.53 (1.35)	13.76 (1.34)	0.553	0.010	-	-	-	-	-	-	-	-
Hostility													
WBI	6.89 (1.04)	8.16 (1.08)	8.77 (1.08)	0.367	0.108	0.620 (-2.091, 3.318)	0.657	-0.400 (-3.073, 2.281)	0.774	-0.241 (-2.990, 2.517)	0.865	0.805 (-1.922, 3.569)	0.570
LI	7.32 (1.11)	8.82 (1.16)	8.39 (1.17)	0.343	0.576	0.861 (-2.045, 3.745)	0.565	-1.201 (-4.099, 1.660)	0.419	-	-	-	-
NI	7.05 (1.10)	7.69 (1.20)	9.32 (1.19)	0.811	0.071	-	-	-	-	-	-	-	-

Abbreviations: EMM Estimated Marginal Means; SE Standard Error; WBI Well-Being Intervention; LI Lifestyle Intervention; NI No Intervention

^a All models were adjusted for school, sex, and socioeconomic status

^b Within-group effect from baseline to post-test

^c Within-group effect from baseline to 6-months

^d Group-by-time effect from baseline to post-test with NI as the reference level

^e Group-by-time effect from baseline to 6-months with NI as the reference level

^f Group-by-time effect from baseline to post-test with LI as the reference level

^g Group-by-time effect from baseline to 6-months with LI as the reference level

Table 5. Changes in primary and secondary binary outcomes for the intervention (WBI and LI) and control (NI) groups.

Outcome	Baseline	Post-test	6-months	AOR ^a (post-test)	<i>p</i>	AOR ^a (6-month)	<i>p</i>	AOR ^b (post-test)	<i>p</i>	AOR ^b (6-months)	<i>p</i>
	N (%)	N (%)	N (%)	OR (95% CI)		OR (95% CI)		OR (95% CI)		OR (95% CI)	
Binge Drinking											
WBI	5 (8.5)	5 (8.5)	6 (10.2)	0.589 (0.013, 27.379)	0.787	0.772 (0.019, 31.838)	0.891	0.661 (0.019, 22.824)	0.819	0.203 (0.005, 8.012)	0.395
LI	5 (12.2)	5 (12.2)	3 (7.3)	0.390 (0.008, 17.993)	0.630	0.157 (0.004, 6.660)	0.332	-	-	-	-
NI	3 (6.8)	3 (6.8)	6 (13.6)	-	-	-	-	-	-	-	-
At-risk drinkers											
WBI	10 (16.9)	10 (16.9)	13 (22.0)	5.426 (0.142, 207.009)	0.363	0.011 (0.0002, 0.783)	0.038	0.264 (0.009, 7.790)	0.441	0.049 (0.001, 1.570)	0.088
LI	10 (24.4)	7 (17.1)	6 (14.6)	1.433 (0.030, 68.967)	0.856	0.0005 (0.000, 0.059)	0.002	-	-	-	-
NI	7 (15.9)	5 (11.4)	13 (29.5)	-	-	-	-	-	-	-	-
Tobacco smoking											
WBI	12 (20.3)	10 (16.9)	7 (11.9)	5.106 (0.061, 429.138)	0.471	0.089 (0.002, 4.483)	0.226	0.140 (0.003, 6.126)	0.308	1.929 (0.051, 72.530)	0.722
LI	12 (29.3)	9 (22.0)	7 (17.1)	0.713 (0.005, 101.832)	0.894	0.171 (0.002, 11.982)	0.415	-	-	-	-
NI	8 (18.2)	5 (11.4)	6 (13.6)	-	-	-	-	-	-	-	-
E-cigarettes use											
WBI	9 (15.3)	4 (6.8)	4 (6.8)	0.735 (0.037, 14.604)	0.840	0.063 (0.003, 1.238)	0.069	0.610 (0.022, 16.883)	0.771	4.086 (0.155, 107.714)	0.399
LI	4 (9.8)	2 (4.9)	3 (7.3)	0.449 (0.013, 15.811)	0.659	0.257 (0.012, 5.539)	0.386	-	-	-	-
NI	4 (9.1)	2 (4.5)	6 (13.6)	-	-	-	-	-	-	-	-
Cannabis smoking											
WBI	9 (15.3)	6 (10.2)	10 (16.9)	0.000 (0.000, 0.018)	0.003	0.003 (0.000, 15.555)	0.181	49086.467 (8.644, 278731300)	0.014	32.119 (0.004, 254189.2)	0.449
LI	7 (17.1)	8 (19.5)	6 (14.6)	0.412 (0.000, 1649.648)	0.834	0.087 (0.000, 491.427)	0.579	-	-	-	-
NI	5 (11.4)	7 (15.9)	7 (15.9)	-	-	-	-	-	-	-	-
Physical activity											

WBI	30 (50.8)	22 (37.3)	22 (37.3)	1.301 (0.225, 7.516)	0.769	2.372 (0.413, 13.626)	0.333	1.205 (0.208, 6.971)	0.835	1.886 (0.329, 10.808)	0.476
LI	19 (46.3)	19 (46.3)	18 (43.9)	1.568 (0.244, 10.082)	0.636	4.474 (0.671, 29.834)	0.122	-	-	-	-
NI	22 (50)	16 (36.4)	10 (22.7)	-	-	-	-	-	-	-	-
Sport activity											
WBI	35 (59.3)	25 (42.4)	26 (44.1)	1.492 (0.184, 12.116)	0.708	1.781 (0.211, 15.047)	0.596	0.902 (0.095, 8.554)	0.928	0.528 (0.052, 5.347)	0.589
LI	28 (68.3)	25 (61.0)	17 (41.5)	1.346 (0.133, 13.634)	0.801	0.940 (0.083, 10.597)	0.960	-	-	-	-
NI	25 (56.8)	16 (36.4)	17 (38.6)	-	-	-	-	-	-	-	-
Fruits and vegetables consumption											
WBI	40 (67.8)	34 (57.6)	34 (57.6)	2.687 (0.377, 19.142)	0.324	1.629 (0.240, 11.066)	0.617	0.644 (0.095, 4.366)	0.652	2.822 (0.393, 20.284)	0.303
LI	21 (51.2)	19 (46.3)	21 (51.2)	1.729 (0.247, 12.126)	0.581	4.609 (0.585, 36.286)	0.147	-	-	-	-
NI	30 (68.2)	21 (47.7)	21 (47.7)	-	-	-	-	-	-	-	-
Healthy diet at home											
WBI	37 (62.7)	32 (54.2)	31 (52.5)	2.600 (0.456, 14.831)	0.282	1.415 (0.260, 7.716)	0.688	0.209 (0.037, 1.174)	0.075	1.216 (0.211, 7.004)	0.827
LI	24 (58.5)	17 (41.5)	20 (48.8)	0.543 (0.088, 3.363)	0.512	1.721 (0.260, 11.383)	0.573	-	-	-	-
NI	26 (59.1)	20 (45.5)	20 (45.5)	-	-	-	-	-	-	-	-
Allostatic overload											
WBI	10 (16.9)	9 (15.3)	15 (25.4)	6.036 (0.862, 42.266)	0.070	1.410 (0.296, 6.712)	0.666	0.044 (0.004, 0.528)	0.014	0.102 (0.017, 0.614)	0.013
LI	10 (24.4)	1 (2.4)	4 (9.8)	0.267 (0.018, 3.895)	0.334	0.144 (0.022, 0.919)	0.040	-	-	-	-
NI	10 (22.7)	3 (6.8)	12 (27.3)	-	-	-	-	-	-	-	-

Abbreviations: WBI Well-Being Intervention; LI Lifestyle Intervention; NI No Intervention

^a Reference level: NI, baseline

^b Reference level: LI, baseline