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RESEARCH ARTICLE

Regular consumption of HolisFiit, a polyphenol-rich extract-based food supplement, improves mind and body well-being of overweight and slightly obese volunteers: a randomized, double-blind, parallel trial

Cindy Romain[a], Pedro Emilio Alcaraz[b], Linda Haiwon Chung[b] and Julien Cases[a]

[a]FYTEXIA, ZAE Via Europa, 3 rue d'Athènes, Vendres, France; [b]Research Center in High Performance Sport-UCAM Universidad Católica de Murcia, Murcia, Spain

ABSTRACT

Modern lifestyles face growing demands for natural solutions to help improve general well-being. Accordingly, mind-body activities such as yoga have considerably grown. However, beneficial effects require regular workout. Besides, literature suggests that polyphenols may demonstrate positive effects on both mental and physical health. Overweight and obese volunteers, for which well-being might be perceived degraded, were included in a 16-week double-blind, randomized and parallel trial with a daily supplementation of HolisFiit®, a polyphenol-rich food supplement. Body composition was assessed by dual-energy X-ray absorptiometry (DXA) technology; well-being was evaluated with both, Athens Insomnia Scale (AIS) and components from Short Form-36 questionnaire (SF-36). Body composition significantly rebalanced by 7.7% ($p = .019$) of the lean-to-fat mass ratio. Also, sleep quality significantly improved by 43% ($p = .00015$) as well as both physical and mental components from SF-36, respectively by 10% ($p = .004$) and 7% ($p = .021$). These data altogether, suggest that regular consumption of HolisFiit®, might significantly improve mind and body well-being.

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Holistic well-being; mental component; physical component; balanced body composition; sleep quality

Introduction

The pursuit of well-being is a universal quest, indivisible from individual and global health. Recognizing this salient fact since 1948, the World Health Organization (WHO) integrated the importance of well-being in the official definition of health. This is described as: "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO 1948). Over the last three decades, the notion of "well-being" has significantly evolved. No longer seen only in terms of basic human needs and rights, living standards and objective conditions of life, well-being currently integrates the experience of feeling mentally and physically good as well as satisfied (Dodge et al. 2012).

Such a holistic vision of well-being and health, supported by current scientific literature (Diener et al. 2003; Loretto et al. 2005) and by recommendations from public health authorities, has clearly contributed to the rise in popularity of self-help approaches to well-being (Sointu 2005). Besides, the pace of daily life is perpetually challenging and people are looking for new natural solutions in attempts to convert the resulting stress and anxiety to a more balanced lifestyle.

Among holistic approaches to well-being improvement, mind-body activities, such as yoga, pilates, meditation or tai chi have grown dramatically in recent years. Yoga practice is among the most popular, with an estimate of 250 million practitioners worldwide, including over 36 million US adults in 2016 (Yoga in America study 2016). This 3000-year-old Indian discipline, based on an interdependence of body and mind, was introduced to Western culture during 19th century. It typically combines stretching exercises with deep breathing and meditation. In the past few decades, abundant clinical trials brought the positive effects of yoga on health to light in a wide range of conditions, from prevention to therapy (Field 2011). Thus, yoga practice was shown to provide beneficial effects on psychological parameters of mental health, including anxiety (Doria et al. 2015), stress (Michalsen et al. 2005) and depression (Uebelacker et al. 2010). Additionally, several studies highlight improvements of steadiness and agility (Polsgrove et al. 2016) as well as of muscular strength and anthropometric parameters in yoga

CONTACT J. Cases jcases@fytexia.com Fytexia SAS, ZAE via Europa, 3, rue d'Athènes, Vendres 34350, France

practitioners (Halder et al. 2015), altogether contributing to an enhanced functioning and bodily fitness. The mechanism would be elicited through down-regulation of both the hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic nervous system (SNS), leading to decreased levels of cortisol, markers of inflammation, and of blood glucose and lipids, as well as of heart rate and blood pressure (Ross & Thomas 2010). Jointly, these endpoints clearly contribute to improve individual well-being in terms of both mental and physical health (Akhtar et al. 2013). It is noteworthy that well-being is the main reported motivator for engaging in yoga (Brems et al. 2015; Quilty et al. 2003). Nevertheless, all these studies also pointed out inevitable barriers to practice, for which lack of time and availability represent the main reasons for missing or even for ceasing workout (Brems et al. 2015; Quilty et al. 2003).

HolisFiit® is an innovative food supplement consisting of a blend of natural bioactive polyphenol compounds, mainly from the flavonoid family (i.e. flavanols, flavanones and anthocyanins), and providing natural caffeine and vitamin B3. Beneficial effects of flavonoids have been demonstrated for several health concerns, primarily those linked to their ability to maintain or rebalance oxidative homeostasis (Heim et al. 2012). Moreover, the recent scientific literature suggests healthful effects of these compounds on vascular function integrity as shown by an improved flow mediated dilation (FMD), an indication that flavonoids may influence vasodilation and blood perfusion in tissues and organs (Spencer & Crozier 2012). The beneficial actions of flavonoids on oxidative stress and vascular function, combined with invigorating effects of both caffeine and vitamin B3, might contribute to improve the flow of blood and energy, leading to a sustainable enhancement of well-being.

The aim of this pilot study was to investigate whether a chronic supplementation with HolisFiit® could improve the general well-being of overweight and slightly obese, but otherwise healthy volunteers.

Materials and methods

Ethics statement

The study was approved by the Comité de ética de la UCAM (Universidad Catolica San Antonio de Murcia, Spain) and conducted per the guidelines laid out in the Declaration of Helsinki and in compliance with Good Clinical Practices defined in the ICH Harmonized Tripartite Guideline. All participants were informed about the study procedures and signed written informed consents before entering the study.

Participants

Thirty-three volunteers (17 men and 16 women) were recruited through advertisements in the region of Murcia in Southern Spain.

Inclusion criteria comprised ages 30 to 50 years, overweight to slightly obese (BMI: 25–35) but otherwise healthy volunteers of both sexes. Key exclusion criteria were the existence of a metabolic or/and chronic disease; allergy to carrot, grape, grapefruit, green tea, caffeine or yerba mate; current involvement or involvement within the previous 6 months in a chronic supplementation program; smoking cessation; high alcohol consumption; pregnancy; breastfeeding and menopausal women.

Study design

The study was designed as a 16-week, randomized, double-blind, parallel group *placebo*-controlled clinical trial. Volunteers were randomized using a simple block randomization of 1:1 with an additional stratification for sex. Once enrolled, subjects received either HolisFiit® supplement ($n = 17$) or a visually identical placebo ($n = 16$). They were instructed to ingest 1000 mg daily of the supplement or the *placebo* in two 500 mg capsules for 16 weeks, one in the morning at breakfast and one at lunchtime. Participants reported to the UCAM Research Center at baseline at week zero (W0) and at the end of the study (W16).

Test supplement

HolisFiit®, developed by FYTEXIA, is principally obtained from alcohol and water extraction of grapefruit (*Citrus paradisi* Macfad.), grape (*Vitis vinifera* L.) and yerba mate (*Ilex paraguariensis* A.St.-Hil.); by water extraction of green tea (*Camellia sinensis* L. Kuntze) and black carrot (*Daucus carota* L.). HolisFiit® provides bioactive compounds, especially polyphenols from flavonoids, delivering flavanones, anthocyanins and flavanols, and natural components of the methylxanthine family from both an extract of green tea and an extract of yerba mate leaves as well as vitamin B3. HolisFiit® complies with regulations on food contaminants and on banned and prohibited substances. The *placebo* product was 100% maltodextrin, which is polyphenol-, methylxanthine- and vitamin B3-free. Both HolisFiit® and *placebo* were supplied in 500 mg capsules of identical appearance and flavor.

Supplement was analyzed by means of high performance liquid chromatography (HPLC). An Agilent

HPLC 1260 apparatus (software Openlab CDS chemstation edition, Agilent Technologies, Santa Clara, CA) coupled with diode array detector was used. Separations were carried out by means of a Zorbax Stablevond SB-C18 column (4.6 × 2 mm; 5 µm particle size). To detect different phenolic classes, two different analytical methods were adopted: one for bioflavonoids and caffeine and one for anthocyanins.

For bioflavonoids and caffeine, mobile phase A consisted of 6% acetic acid, mobile phase B was 5% acetic acid and 30% acetonitrile and mobile phase C was 100% acetonitrile. The program was as follows: (a) 5 min 100% A; (b) 5–10 min linear gradient from 0 to 40% B; (c) 10–15 min linear gradient from 40 to 60% B; (d) 15–20 min linear gradient from 60 to 75% B; (e) 20–25 min linear gradient from 75 to 90% B; (f) 25–30 min linear gradient from 90 to 100% B; (g) 30–35 min linear gradient from 0 to 100% C; (h) 35–40 min 100% C; and (i) 40–45 min linear gradient from 0 to 100% A. Monitoring was performed at 280 nm at a flow rate of 1 mL/min and injection volume of 25 µL. Flavanones, flavanols and caffeine were expressed as naringin, catechin and caffeine, respectively.

For anthocyanins, mobile phase A consisted of 10% formic acid and 3% acetonitrile and mobile phase B was 10% formic acid and 50% acetonitrile. The program was as follows: (a) 0–20 min linear gradient from 6 to 20% B; (b) 20–35 min linear gradient from 20 to 40% B; (c) 35– 40 min linear gradient from 40 to 60% B; (d) 40–45 min linear gradient from 60 to 90% B; (e) 45–50 min 90% B; (f) 50–55 min linear gradient from 90 to 100% B; (g) 55–60 min 100% B; and (h) 60–65 min linear gradient from 0 to 94% A. Monitoring was performed at 520 nm at a flow rate of 0.8 mL/min and injection volume of 10 µL. Anthocyanins were expressed as kuromarin chloride.

Diet and exercise

Throughout the course of the study, volunteers were instructed by a dietician to consume a normal calorie and balanced diet corresponding to their individual needs for determining their specific basal metabolic rate (BMR), calculated from the revised equation of Harris Benedict (Roza & Shizgal 1984), and adjusted per their individual level of physical activity. Subjects were also asked to maintain their usual level of physical activity.

Body composition assessment

At the beginning (W0) and at the end (W16) of the study period, body weight (kg) and body composition were monitored in the morning with volunteers in a fasted state and wearing light clothing. Body composition was assessed using dual energy x-ray absorptiometry (DXA)-scan of the whole body (XR-46; Norland Corp., Fort Atkinson, WI). Discrimination of whole-body fat mass (FM) and lean mass (LM) was assessed with a computerized analysis of DXA-scan (Software Illuminatus DXA 4.4.0, Visual MED, Inc., Charlotte, NC and Norland CooperSurgical Company, Minneapolis, MN).

Questionnaires

Subjective sleep complaints and corresponding impacts on well-being and functioning were assessed with the 8-item Athens Insomnia Scale (AIS-8) (Soldatos et al. 2000). This self-administrated questionnaire incorporates eight questions rated on a 4-point Likert scale, from 0 (no problem at all) to 3 (very serious problem).

The subjective feeling of both mental and physical health was assessed using the validated Medical Outcomes Study 36-item Short-Form (SF-36) General Health Survey as previously described (Ware & Sherbourne 1992). The questionnaire contains 36 questions and is self-administrated. The SF-36 assesses quality of life and well-being in eight multi-item scales, gathered as both a physical component summary (PCS) and a mental component summary (MCS). The responses are based on a Likert scale of 3, 5 or 6 points. Volunteers completed SF-36 and AIS questionnaires both upon inclusion (W0) and completion of the study (W16) at the research center, in the presence of the study investigator.

Statistical analysis

Data sets were analyzed using Statview software version 4.51.1 (Abacus Concepts, Berkeley, CA). The data are expressed as mean ± standard error to the mean (SEM). Changes within and between groups at W0 and W16 were analyzed using, respectively, paired and unpaired Student's t-test. A minimum value of $p < .05$ was selected as the threshold for statistical significance.

Results

Characterization of the bioactive compounds profile of the supplement

The total bioactive content was measured to correspond to 30.6/100 g dry matter. Bioflavonoid content was measured at 25/100 g, of which epigallocatechin

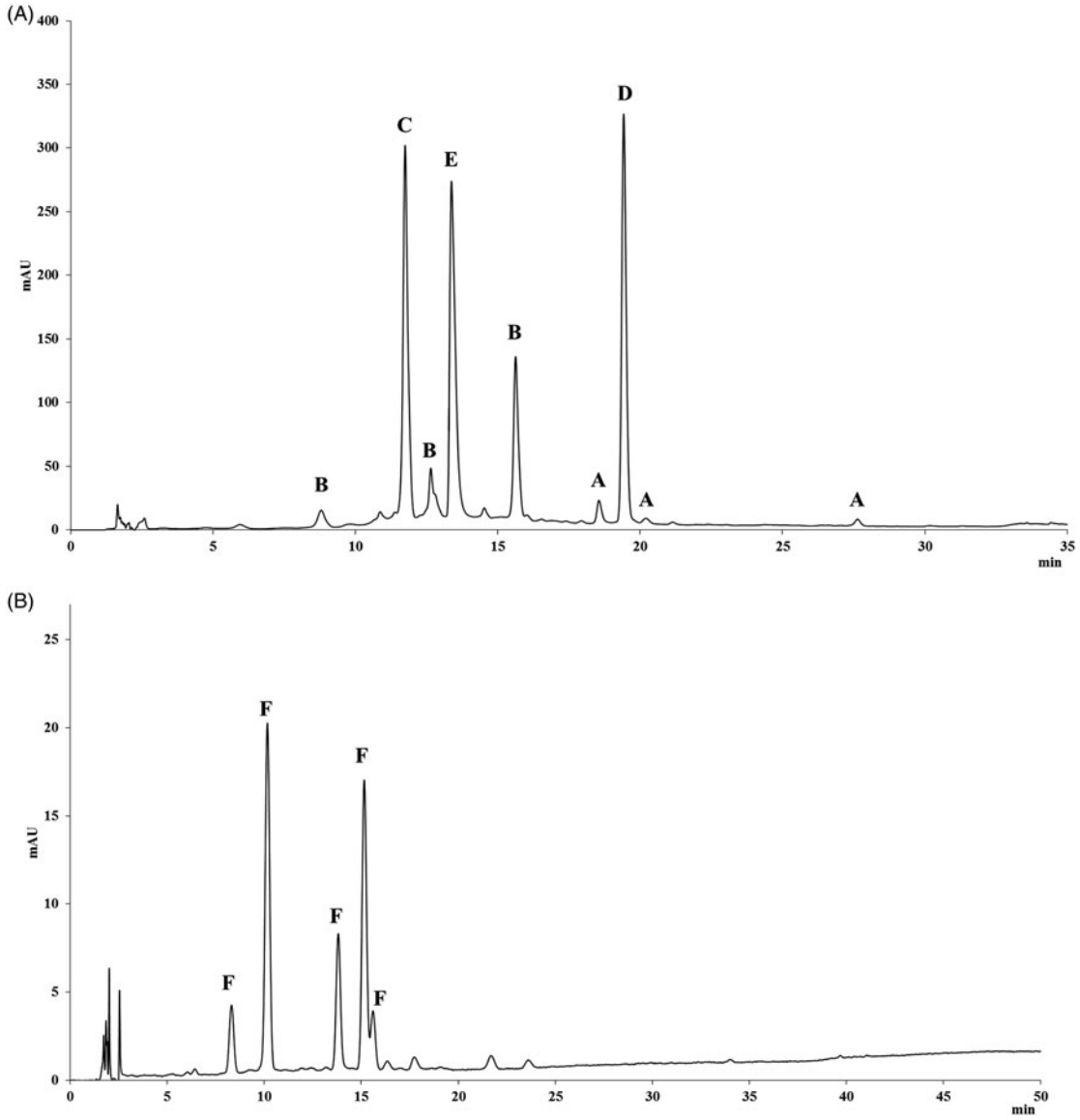

Figure 1. HPLC fingerprint of the supplement. Measurement of bioactive components at 280 nm (A) and 520 nm (B). (A = flavanones; B = flavanols; C = EGCG; D = naringin; E = caffeine; F = anthocyanins).

gallate (EGCG) was measured at 9/100 g, naringin was measured at 8/100 g, anthocyanins were measured at 0.15/100 g, caffeine was measured at 4/100 g and vitamin B3 was measured at 1.6/100 g (Figure 1(A), (B)). Thus, a 1000 mg daily dose corresponds to 306 mg of total bioactive compounds ingested, i.e. 250 mg of total bioflavonoids of which 90 mg of EGCG, 80 mg of naringin and 1.5 mg of anthoyanins, also 40 mg of caffeine and 16 mg of vitamin B3.

Participant characteristics

All 33 volunteers enrolled completed the 16-week study period. Baseline anthropometric characteristics of volunteers, stratified by supplementation, are summarized in Table 1. No statistical differences were seen for these parameters between the two groups.

Table 1. Baseline participant characteristics.

	All volunteers	Placebo group	HolisFiit® group
N	33	16	17
Sex (M/F)	17/16	9/7	8/9
Age (years, mean ± SEM)	40.1 ± 1.1	40.1 ± 1.5	40.1 ± 1.6
Height (cm, mean ± SEM)	169.4 ± 1.6	170.7 ± 1.8	168.2 ± 2.7
Weight (kg, mean ± SEM)	86.4 ± 2.2	89.9 ± 2.8	83.6 ± 3.2
BMI (kg/m^2, mean ± SEM)	30.2 ± 0.5	30.9 ± 0.8	29.7 ± 0.7

Body composition

After the 16-week study period, volunteers in the HolisFiit® group achieved a significant weight loss of

1.1 ± 0.6 kg ($p = .047$) whereas members of the placebo group did not show any variation (Figure 2).

Body-weight loss in HolisFiit® group accounted for a significant decrease in total body FM, corresponding to 1.6 ± 0.8 kg ($p = .028$). Despite the loss, LM increased, but although the trend was strong, this was not statistically significant ($p = .159$). Body composition of the placebo group remained constant after 16 weeks (Figure 2).

After 16 weeks of daily supplementation, the lean-to fat mass ratio (LM/FM) significantly increased compared to the placebo group: 7.4% versus 0.8% ($p = .019$), respectively (Figure 3).

AIS questionnaire

Volunteers from the supplemented group and concerned with AIS items showed significant improvements in five out of eight items of the AIS questionnaire after 16 weeks of daily supplementation (Figure 4).

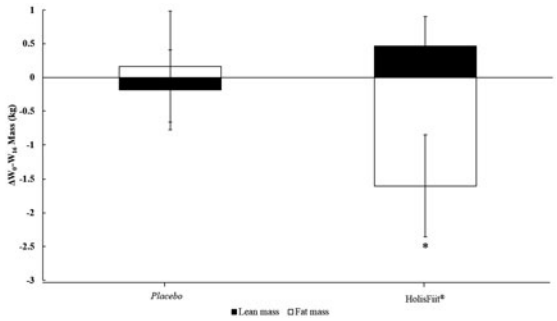

Figure 2. Body weight (kg) and body composition (kg) variations between baseline (W0) and completion of the study (W16). Values are means ± SEM, $n = 16$ (placebo) or $n = 17$ (HolisFiit®). *Indicates an intragroup difference between W0 and W16, $p < .05$.

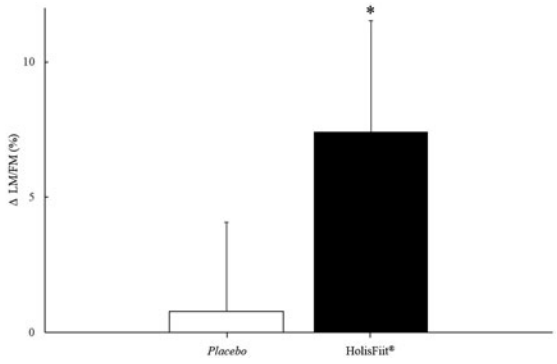

Figure 3. Lean-to-fat mass ratio (LM/FM) variation (%) between baseline (W0) and completion of the study (W16). Values are means ± SEM, $n = 16$ (placebo) or $n = 17$ (HolisFiit®). *Indicates an intragroup difference between W0 and W16, $p < .05$.

Respective percent improvements were shown for awakening during the night (38%, $p = .040$), total sleep duration (50%, $p = .025$), sleep quality (43%, $p = .039$), well-being during the day (67%, $p = .013$) and functioning capacity during the day (80%, $p = .008$). In the placebo group, scores for individual items showed no statistical difference. Compared to baseline, total scores in the AIS questionnaire were significantly improved in both groups, but with a strong and higher improvement in volunteers supplemented with HolisFiit®: 43% ($p = .00015$) versus 17% ($p = .022$) for the placebo group (data not shown).

SF-36 questionnaire

Among the eight items in the SF-36 questionnaire, four (two in each component) were excluded from summary scores; since mean scores were high (above 85 points out of 100), no beneficial improvement was intended. PCS, which included both bodily pain and general health, was significantly improved in the HolisFiit® group by 10.0 ± 4.6% ($p = .004$), whereas the PCS of volunteers from the placebo group remained stable (Figure 5(A)). Similarly, MCS, included vitality and emotional well-being sub-scores; it was improved by 7.0 ± 3.3% ($p = .021$) after the 16-week supplementation with HolisFiit®, whereas the slight increase in the placebo group was not statistically significant (Figure 5(B)). The global SF-36 score, covering both PCS and MCS results, improved with the 16-week supplementation by 11.0 ± 3.4% ($p = .002$); no significant change was experienced in the placebo group (Figure 5(C)).

Discussion

This prospective study highlights beneficial effects of a 16-week daily supplementation with HolisFiit®, a polyphenol-rich extract-based food supplement developed from fruit and vegetables, on both body composition and on subjective perception of mental and physical health, altogether contributing to an improved general well-being.

The 16-week supplementation with HolisFiit® significantly induced a weight loss of 1.6%. Although moderate, this body mass decrease is clearly favorable in terms of body composition. Indeed, supplemented-volunteers showed a significant decrease of total body FM of 5.3%, while LM, including muscle, organs and tissues, remained stable. Consequently, LM/FM, a global indicator of body composition balance, is significantly improved with a 7.7% increase; such positive

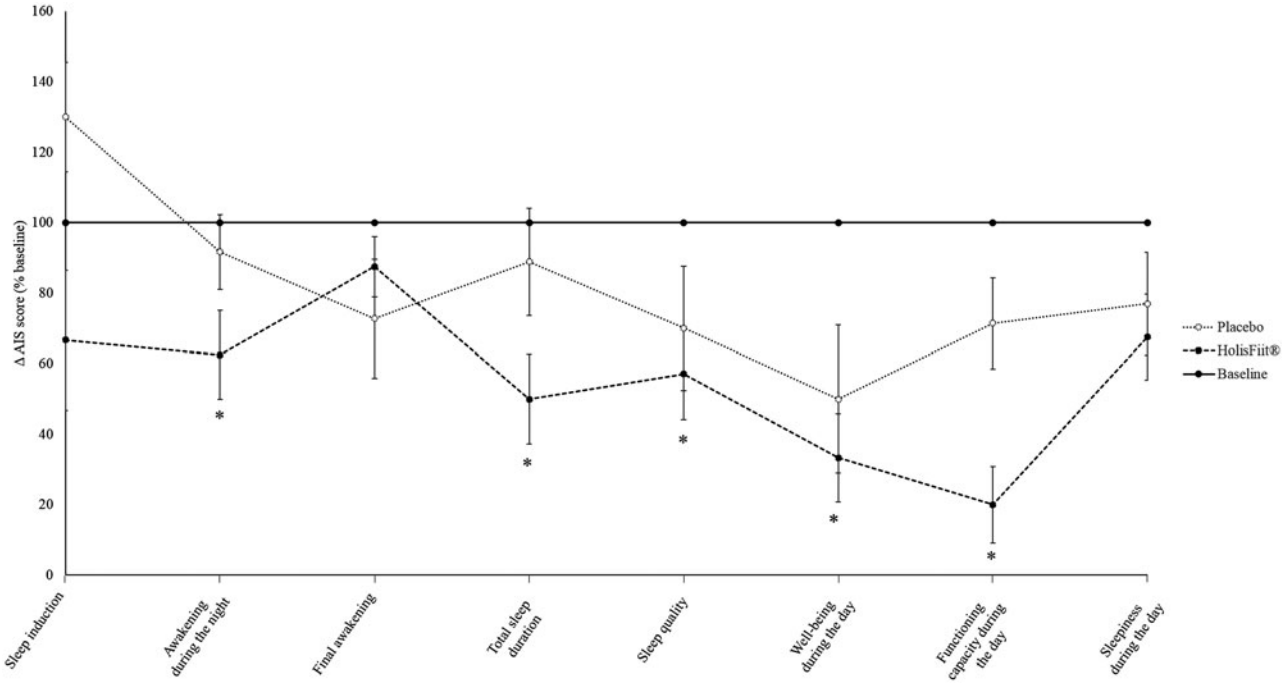

Figure 4. AIS 8-item score variation between baseline (W0) and completion of the study (W16). Values are means ± SEM, $n = 16$ (placebo) or $n = 17$ (HolisFiit®). *Indicates an intragroup difference between W0 and W16, $p < .05$.

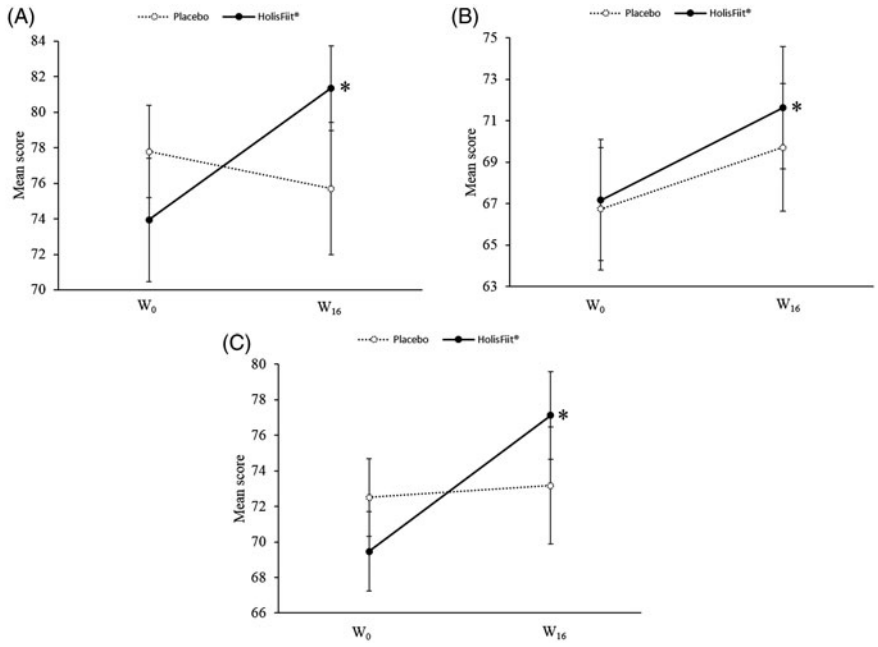

Figure 5. SF-36 physical component summary (A), mental component summary (B) and total score (C), at baseline (W0) and at the end of the study (W16). Values are means ± SEM, $n = 16$ (placebo) or $n = 17$ (HolisFiit®). *Indicates an intragroup difference between W0 and W16, $p < .05$.

shifts were not achieved in the placebo group. Several authors have previously described beneficial effects of regular polyphenol intake for body composition management, such as flavanols from green tea that have been reported to improve body composition in several human studies (Nagao et al. 2007; Wang et al. 2010), probably *via* an increased oxidation of fat and promoted energy expenditure (Rains et al. 2010). Other flavonoids in HolisFiit® could act synergistically with green tea catechins, including flavanones from grapefruit for which several clinical trials demonstrated benefits of supplementation for rebalancing body composition (Cases et al. 2015a; Dallas et al. 2014; Fujioka et al. 2006).

It is noteworthy that a strong relationship exists between excessive body weight and reported general well-being (De Zwaan et al. 2009; Jorm et al. 2003). In the past two decades, decrease in body fat in overweight or obese individuals has even been correlated with physical well-being, for which researchers have previously reported significant improvements of bodily pain, physical functioning and vitality (Cases et al. 2015b; Fontaine et al. 1999; Jensen et al. 2004). Thus, the beneficial effects of HolisFiit® supplementation on body composition could positively affect, therefore and at least in part, the self-reported improvement of PCS assessed with SF-36 questionnaire.

Behind this potential impact of body composition on physical health, other mechanisms of action could explain the global improvement in the score of the SF-36 questionnaire. Recently, several authors demonstrated the capacity of polyphenolic compounds in improving endothelial function in patients with manifest cardiovascular disease, as well as in healthy individuals (Vita 2005). Notably, both green tea and grape consumption, whether short- or long-term, has been associated with improved endothelial function in clinical trials, as assessed by improvements in FMD (Li et al. 2013; Ras et al. 2011). Proposed principal mechanisms by which flavonoids would mediate improved FMD are their ability to modulate the bioavailability of nitric oxide (NO) in the endothelium through activation of endothelial nitric oxide synthase (eNOS), and the inhibition of nicotinamide adenine dinucleotide phosphate (NADPH) oxidase, together leading to an endothelium-dependent relaxation (Grassi et al. 2013). The beneficial effects of polyphenols on FMD could positively impact well-being, namely regarding the MCS of the SF-36 questionnaire. Indeed, several authors showed inverse correlations between endothelial function and negative moods, such as depression (Cooper et al. 2011), anxiety (Narita et al. 2007), hostility, anger and fatigue (Cooper et al. 2011). Therefore, the improved FMD can lead to increased cerebral blood flow, which is involved in the regulation of emotion and change in mood (Cooper et al. 2010; Hoshi et al. 2011). Moreover, there are recent reports of significant associations between endothelial function, assessed by FMD, and self-reported sleep quality and rapid-eye-movement sleep (Behl et al. 2014; Cooper et al. 2014). In this study, the overall sleep quality of volunteers improved by 43% after the 16-week supplementation with HolisFiit®. Indisputably, sleep quality and mental and physical health are interdependent factors that not only promote each other, but contribute to the general feeling of improved general well-being.

Regular practice of yoga shows similar effects on improvement of well-being (Field 2011), with concomitant improvement of sleep, physical functioning and mental health. In this regard, supplementation with HolisFiit® could potentiate the effectiveness of yoga workouts and be used as a complementary approach by practitioners, or individuals seeking an additional natural and holistic solution to improve both their mind and body well-being.

Conclusions

This prospective study demonstrated the beneficial effects of HolisFiit®, a natural product blending polyphenols extracted from fruit and vegetables, for the improvement of general well-being. The 16-week daily supplementation of overweight and slightly obese individuals was associated with a positive rebalancing of body composition, as demonstrated by a significant decrease in total body FM and, at the same time, the preservation of LM. These physiological improvements were concomitantly associated with improvements in both physical and mental health, as well as sleep quality; the combined benefits leading to an enhancement of subjective general well-being.

In their capacity to improve well-being through FMD, further investigations need to be conducted to gain insight into mechanisms of action of bioactive components within the supplement, especially regarding polyphenols. Moreover, a study involving a larger population and incorporating a yoga practitioner arm would serve to investigate the potential synergistic benefits of HolisFiit® in direct association with the practice.

Disclosure statement

Fytexia is involved in the research & development and marketing & sales of polyphenol extracts from various fruit and vegetables regularly consumed within the Mediterranean diet for food and nutraceutical industries. Therefore, Fytexia has a commercial interest in this publication. UCAM was paid by Fytexia to perform and report the scientific work that formed the basis of this publication. All authors, Fytexia and UCAM, declare that the data in this report represent a true and faithful representation of the work that has been performed.

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