The effect of herbal formula consisting of *Curcuma xanthorrhiza*, *Curcuma longa* and *Phyllanthus niruri* on quality of life: Randomized controlled trial

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**Abstract.** The herbal ingredients consisting of temulawak (*Curcuma xanthorrhiza* Roxb.), turmeric (*Curcuma longa* L.), and meniran (*Phyllanthus niruri* L.) have been used to improve physical fitness. However, the effect of these herbs on the quality of life is not yet known. This study aims to assess the effect of physical fitness herbal formula on quality of life. This study used a randomized controlled trial design. A total of 100 subjects were given herbal formula and 101 subjects were given a placebo. Herbal formula was made by boiling 4 cups (800 ml) of water until it boils, adding simplicia then reducing the heat, waiting for about 15-30 minutes until only two cups (400 ml) of water remained, filtered and put in a special thermos. The herbs and placebo were taken twice a day for 42 days. Before the study and on day 42th, subjects were examined for their quality of life using the Short Form 36 (SF-36) questionnaire. The results showed that there were no significant changes in the mental component summary and the dimensions of physical function, role of emotions, energy, mental health, social function, and general health. However, in the physical component summary and the dimensions of physical role and pain there was a significant increase in the quality of life (p=0.032; p=0.005; p=0.017). In conclusion, the physical fitness herbal formula can improve the physical component summary of quality of life, especially the dimensions of physical roles and pain.

1. **Introduction**

Indonesia is home to one of the greatest biodiversity in the world with about 143 million hectares of rainforest. Hundreds of tribes living in and around forests and villages each develop their own traditional medicine. Indonesia is a country in Southeast Asia that has more than 30 thousand species of medicinal plants. It is estimated that of these, 6000 species have various biological activities and 1000 species are commonly used in traditional medicines or Jamu in Indonesia. Jamu consists of one of the botanical ingredients or a mixture of medicinal plants, and is used for the prevention or treatment of disease [1].

Temulawak (*Curcuma xanthorrhiza* Roxb.), turmeric (*Curcuma longa* L.), and meniran (*Phyllanthus niruri* L.) are medicinal plants that are often used in Indonesia. The combination of these plants is often used to improve fitness. Based on previous research that a mixture of temulawak, turmeric, and meniran can help improve cardiovascular fitness and is safe for use on liver and kidney function. But the benefits of this herb for improving the quality of life are not known for certain [2].

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Quality of life (QoL) is a subjective perception of one's own well-being in a socio-cultural context, or as the satisfaction of one's desires in achieving an ideal level of well-being. Measuring the health status of an individual or population is an important first step in assessing the impact of a health intervention [3]. One form of measuring the quality of life is the Short Form 36 (SF-36). The SF-36 is a questionnaire consisting of 36 questions to assess the quality of life that has been used by various studies globally and is standardized. SF-36 is a general instrument that describes the quality of life in the population and has been validated [4].

The purpose of this study was to determine the effect of fitness herbs consisting of temulawak, turmeric and meniran on the quality of life as measured using the SF-36 questionnaire.

2. Material and methods
2.1. Design and population study
The research was conducted at a Islamic boarding school in Sukoharjo Indonesia in October-December 2017. Research design randomized controlled trial. A total of 204 Islamic boarding school students were divided randomly using closed envelopes. A total of 102 students received a herbal concoction and 102 students received a placebo.

The inclusion criteria for this study were male boarding school senior high school students, obtaining permission from the students' parents and being willing to sign the informed consent. Exclusion criteria included having a history of chronic diseases and requiring long-term therapy; previous history of allergies to herbs; and did not get permission from the student's parents. Recruitment and intervention was carried out after obtaining research ethics approval from the Health Research Ethics Commission of the Indonesian Ministry of Health with number LB.02.01/2/KE238/2017.

2.2. Herbal material and preparation
The herbal ingredients consist of temulawak rhizome (Curcuma xanthorrhiza Roxb.), turmeric (Curcuma longa L.), and meniran (Phyllanthus niruri L.). Medicinal plants come from the production garden of the Medicinal Plant and Traditional Medicine Research and Development Center (MPTMRDC), Tawangmangu, Karanganyar, Indonesia. Determination and standardization of plants is carried out at the MPTMRDC Integrated Laboratory. The manufacture of materials and quality control is carried out by the MPTMRDC Quality Control team. Simplisia is packed with a dose of 5 grams of temulawak rhizome, 4 grams of turmeric rhizome, and 3 grams of meniran herbs. The placebo material is mineral water that is specially packaged so that the subject does not know if what is given is mineral water.

Herbal formula is made by boiling 4 cups (800 ml) of water until it boils, adding simplicia then reducing the heat, waiting for about 15-30 minutes until there are only two cups of water (400 ml), filtered and put in a special thermos. The herbal medicine is made by a special officer and distributed to the participants already in thermos. The herbs were made every morning for 42 days. To monitor adherence to drinking herbal medicine according to the recommended volume (200 ml once drink), every participant has a supervisor for drinking herbal medicine.

2.3. Intervention and outcome parameter
The herbal group drank herbal concoction twice a day in the morning and evening for 42 days. The placebo group drank mineral water in a special bottle twice a day for 42 days. Each student has a supervisor who is in charge of ensuring that the herbal medicine or placebo is taken according to the rules and records the order of the students during the study and reports to the researcher if there are complaints from the subject. Measurement of quality of life with SF-36 was performed before and after the intervention.

2.4. Data analysis
The results of measurements of SF-36 before and after drinking herbal medicine were analyzed using the appropriate statistical test software. If the data distribution is normal, the statistical test uses an
unpaired t test. If the data distribution is not normal use the Mann Whitney test. Test the normality of the data using the Kolmogorov-Smirnov test.

3. Results and discussion

The research journey from the screening process to data analysis can be seen in figure 1. Screening was carried out on 215 participants. Eleven participants did not meet the criteria because they did not get permission from the participants' parents so that only 204 participants took part in the study. During the study, there were two participants in the herbal medicine group who dropped out because they had not taken herbal medicine for more than a week. In the placebo group there was one participant who dropped out because he had not taken the placebo for more than a week. So that at the end of the study there were 100 participants from the herbal medicine group and 101 participants from the placebo group who were analyzed.

![Figure 1. Consort diagram.](image)

The characteristics of the participants at the beginning of the study can be seen in table 1. Based on table 1, there was no significant difference between the herbal medicine group and the placebo group (p>0.05). So it can be assumed that both groups have the same baseline. During the study no harmful side effects were reported while the participants were taking herbal medicine.

Research participants were selected from Islamic boarding school students because students in Islamic boarding schools tend to be homogeneous. In addition, the activities and eating patterns of each student also tend to be the same. In Islamic boarding schools it is also easier for researchers and supervisors to drink herbal medicine in controlling subjects to comply with the research protocol. Homogeneous study participants and no significant difference at baseline can reduce the occurrence of bias in the study.
Table 1. Characteristics of participants.

| Variable                      | Herbal Group (n=100) | Placebo Group (n=101) | p   |
|-------------------------------|----------------------|-----------------------|-----|
| Age (years)                   | 16.37 ± 1.26         | 16.37 ± 1.11          | 0.491 |
| Body Mass Index (kg/m²)       | 20.91 ± 2.08         | 21.47 ± 2.79          | 0.055 |

Table 2. Dimensions of SF-36.

| Variable                      | Day   | Herbal Group (n=100) | Placebo Group (n=101) | p   |
|-------------------------------|-------|----------------------|-----------------------|-----|
| Physical functioning          | Day-0 | 87.35 ± 22.60        | 76.58 ± 31.21         | 0.460 |
|                               | Day-42| 91.70 ± 15.41        | 89.80 ± 15.52         | 0.005* |
| Role-physical                 | Day-0 | 82.50 ± 27.18        | 81.19 ± 24.08         | 0.005* |
|                               | Day-42| 85.50 ± 22.24        | 76.24 ± 25.59         | 0.005* |
| Role-emotional                | Day-0 | 76.00 ± 32.16        | 85.15 ± 25.16         | 0.005* |
|                               | Day-42| 82.33 ± 28.21        | 75.25 ± 33.22         | 0.005* |
| Vitality (energy)             | Day-0 | 74.45 ± 12.35        | 73.47 ± 13.15         | 0.005* |
|                               | Day-42| 75.44 ± 8.75         | 75.21 ± 11.96         | 0.005* |
| Mental health                 | Day-0 | 75.64 ± 11.99        | 77.47 ± 12.92         | 0.308 |
|                               | Day-42| 74.75 ± 17.41        | 73.14 ± 18.99         | 0.308 |
| Social functioning            | Day-0 | 73.88 ± 18.13        | 71.29 ± 18.16         | 0.308 |
|                               | Day-42| 78.33 ± 16.38        | 81.41 ± 16.52         | 0.308 |
| Bodily pain                   | Day-0 | 81.68 ± 14.68        | 74.68 ± 19.41         | 0.308 |
|                               | Day-42| 69.50 ± 14.01        | 69.41 ± 15.82         | 0.308 |
| General health                | Day-0 | 72.55 ± 14.40        | 72.43 ± 14.47         | 0.308 |
|                               | Day-42| 72.55 ± 14.40        | 72.43 ± 14.47         | 0.308 |

Table 3. Differences in the mean components of SF-36.

| Variabel                      | Day  | Herbal Group | Placebo Group | p   |
|-------------------------------|------|--------------|---------------|-----|
| Physical component summary    | D-0  | 81.32 ± 14.79| 77.89 ± 19.35| 0.308 |
|                               | D-42 | 85.00 ± 10.77| 81.92 ± 11.45| 0.032* |
| Mental component summary      | D-0  | 75.04 ± 10.59| 76.30 ± 11.47| 0.032* |
|                               | D-42 | 76.48 ± 10.45| 74.96 ± 12.48| 0.032* |

The assessment of each dimension of the SF-36 can be seen in table 2. Of the eight dimensions of the SF-36 assessment, there are two assessment dimensions that show the results of significant differences between the herbal medicine group and the placebo group, namely the dimensions of physical roles and pain (p = 0.005; p = 0.017). For the assessment of each component of SF36 (table 3.) There was a significant difference between the herbal medicine group and the placebo group for the physical component (p = 0.032) but for the mental component there was no significant difference between the groups.
A person’s quality of life is divided into two components of assessment, namely the physical component summary and the mental component summary. The physical component summary consists of dimensions of physical function, physical role, pain and general health. The mental component summary consists of the dimensions of the role of emotion, vitality, mental health, and social functioning [5,6]. Based on the results of this study, it was shown that herbal medicine could significantly increase the participants’ physical components, especially for the dimensions of pain and physical roles. This is most likely due to the curcumin content in temulawak and turmeric, which have analgesic and anti-inflammatory functions [7,8]. Curcuma is also used for antioxidants, detoxification, preventing cancer cells, preventing acne, anti-inflammatory, reducing cholesterol, and increasing appetite [9]. Meniran also contains philanthe, hypophilantin, and triacontanol which are generally known to have immunomodulatory effects [10,11]. Meniran also has the ability as an antioxidant and increases the body’s resistance to disease [12]. So that the interaction of the three plants in herbal medicine has the potential to improve the quality of life of research participants.

This study is in accordance with research conducted by Triyono et al that the composition of temulawak, turmeric, and meniran in herbal hypertension ingredients can improve the quality of life of people with hypertension [13]. Temulawak, turmeric, and meniran in herbal ingredients for diabetes mellitus are also able to improve the quality of life of patients with diabetes mellitus [14]. Another study conducted by Astana et al proved that the addition of temulawak, turmeric, and meniran in hemorrhoidal herbs can improve the quality of life of hemorrhoid sufferers comparable to the standard drug diosmin hesperidin [15].

The limitation of this study is that the study participants were only male, so the results might be different if female participants were included in the study. The age range of young and healthy participants who generally have a good quality of life may differ in results if the measurement is carried out on participants with a wide age range or on people who are sick. Research sites in Islamic boarding schools on the one hand have the advantage that the participants are homogeneous and it is easy to control the intervention so that research bias can be controlled but on the other hand the generalization of the results may be different if applied in a society whose characteristics are very heterogeneous. Further research is highly recommended to involve more male and female participants, a wide age range and in the general public.

4. Conclusion
The physical fitness herbal formula consisting of 5 grams of temulawak rhizome, 4 grams of turmeric rhizome, and 3 grams of meniran herbs for 42 days can improve the quality of life of physical component summary (p=0.032), especially the dimensions of physical roles and pain (p=0.005; p=0.017) but no significant on mental component summary (p=0.510).

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