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WAYS TO IMPROVE THE QUALITY OF LIFE OF PATIENTS WITH METABOLIC SYNDROME: A SYSTEMATIC REVIEW

Actuality. Improvement in health-related quality of life may be a key characteristic and measure of the effectiveness of metabolic syndrome interventions. Lifestyle changes today are one of the leading means of treating this syndrome. Previous studies on the impact of lifestyle changes on quality of life have not provided a clear answer to this question, so a systematic review is appropriate to clarify the evidence.

The purpose. The purpose of the systematic review was to evaluate the impact of lifestyle interventions in adults with metabolic syndrome (MS) on health-related quality of life (HROoL) and its physical, mental and social dimensions.

Materials and methods. Inclusion criteria were: randomized clinical trials (RCTs), the study was conducted in adults (both sexes) who had at least four criteria for MS, a lifestyle intervention, and measurement of HRQoL using a validated questionnaire. Exclusion criteria included studies of a different design than RCTs. Based on the Cochrane Collaboration risk of bias tool, only two RCTs were identified as having a high risk of bias. Databases used were PubMed, Cochrane Library, EMBASE and Google Scholar. Seven RCTs were selected for a systemic review with 1108 study participants.

Research results. The results of the systematic review were mixed. Small improvements were found in physical HRQoL measures in the physical activity lifestyle interventions, but inconsistent changes occurred in one of the RCTs, with better results in the control group. Quality of life related to mental health had a positive effect over time, but without a significant difference in the comparison groups. The overall score was not calculated in most RCTs, meaning changes were not determined.

Conclusion. The findings suggest that lifestyle interventions in the RCTs selected for this systematic review do not provide insight into these effects on HRQoL and this issue requires further research.

Key words. Metabolic syndrome, health-related quality of life, lifestyle intervention.

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ШЛЯХИ ПІДВИЩЕННЯ ЯКОСТІ ЖИТТЯ ПАЦІЄНТІВ З МЕТАБОЛІЧНИМ СИНДРОМОМ: СИСТЕМАТИЧНИЙ ОГЛЯД

Актуальність. Покращання якості життя пов'язаного зі здоров'ям, може бути основною характеристикою та оцінкою ефективності втручань щодо терапії метаболічного синдрому. Зміна способу життя ϵ на сьогоднішній день одним з провідних засобів терапії цього синдрому. Попередні дослідження впливу змін способу життя на його якість не дали однозначної відповіді на це питання, тому систематичний огляд ϵ доречним для уточнення даних.

Мета дослідження. Мета систематичного огляду полягала в тому, щоб оцінити вплив втручань у спосіб життя у дорослих з метаболічним синдромом (МС) на якість життя, пов'язану зі здоров'ям (ЯПЖЗ) та її фізичну, психічну та соціальну складові.

Матеріали та методи дослідження. Критеріями включення були: рандомізовані клінічні дослідження (РКД), дослідження проводилися у дорослих (обох статей), які мали принаймні чотири критерії МС, втручання у спосіб життя, а також вимірювання ЯПЖЗ за допомогою валідованого опитувальника. Критеріями виключення були дослідження іншого дизайну, ніж РКД. На підставі інструменту Cochrane Collaboration для оцінки ризику упередженості було встановлено лише два РКД з високим ризиком похибки. Використаними базами даних були PubMed, Cochrane Library, EMBASE ma Google Scholar. Сім РКД було відібрано для системного огляду з 1108 учасниками дослідження.

Результати дослідження. За результатами систематичного аналізу отримано неоднозначні результати. Незначні покращення були виявлені у фізичних параметрах показників ЯПЖЗ у втручаннях щодо змін способу життя пов'язаних з фізичною активністю, але в одному з РКД відбулися суперечливі зміни, з вищими результатами в контрольній групі. Якість життя, пов'язана з психічним здоров'ям, мала позитивні впливи у динаміці, але без істотної різниці у групах порівняння. Загальна оцінка не розраховувалась в більшості РКД, тобто її зміни не були визначені.

Висновок. Отримані результати свідчать про те, що втручання у спосіб життя згідно з РКД, відібраними для цього систематичного огляду, не дає розуміння щодо цих впливів на ЯЖПЗ і це питання потребує подальших досліджень.

Ключові слова: метаболічний синдром, якість життя пов'язана зі здоров'ям, втручання у спосіб життя.

Introduction. Actuality. Today, metabolic syndrome is one of the main problematic issues in the field of health care in many countries around the world (Kalmykova et al., 2021a; Kalmykova et al., 2021b; Kalmykova, 2023a). The incidence of metabolic syndrome in the population is high. Previously, metabolic syndrome was considered a disease of older people, however, today the percentage of young people with this pathological condition has increased. In Ukraine, the frequency of metabolic syndrome varies from 20 to 35% (in women, the latter occurs 2.5 times more often, and with age the number of patients only increases) (Shaposhnikova et al., 2020; Kalmykova, 2023b; Kalmykova & Kalmykov, 2023; Riabenko et al., 2023).

The criteria for diagnosing metabolic syndrome are the presence of visceral obesity and two of the following four factors: increased waist circumference >94 cm (men) and >80 cm (women), a sustained increase in systolic blood pressure >130 mm Hg or diastolic blood pressure >85 mm Hg. Art. or chronic use of antihypertensive drugs, an increase in blood triglyceride levels >1.7 mmol/l or long-term treatment with statins and a decrease in HDL-C levels <1.05 mmol/l (men); <1.25 mmol/L (women), hyperglycemia >6.1 mmol/L or type 2 diabetes diagnosed (Kalmykova et al., 2018a; Kalmykova & Kalmykov, 2018; Bocharova et al., 2020; Kalmykova et al., 2020; Babinets & Melnyk, 2021; Sergii et al., 2021; Turchyna et al., 2022).

Measuring the outcome of rehabilitation interventions presents a range of issues, including patient-centredness and links to the International Classification of Functioning, Disability and Health, ICD. According to consensus and WHO, the relevant rehabilitation outcomes are "function", "activity" and "social participation". However, improving quality of life (QoL) may be the ultimate goal of medicine. That is, studies of the interaction between "symptoms", "activity", "social participation" and quality of life are significant (Ravnborg & Storr, 2008).

The QoL of patients with metabolic syndrome has been the subject of research by a significant number of scientists Vetter et al. (2011); Lee et al. (2012); Saboya et al. (2016); Marcos-Delgado, et al. (2020); Limon et al. (2020); Conde-Pipó et al. (2022). They found that MS is associated with decreased health-related quality of life (HRQoL), however, this association is complex as it may differ between genders or in the presence of obesity and depression. In addition, some results are conflicting and suggest that metabolic syndrome itself was not associated with a person's quality of life, but other factors such as obesity, depression and a greater burden of disease may significantly influence the quality of life of this population

(Ford & Li 2008; Vetter et al., 2011; Lee et al., 2012). There is also a study by Marcos-Delgado et al. (2020) where it was shown that MS may negatively affect HRQoL in aggregate physical dimensions, but this relationship was absent for psychological aspects of HRQoL

According to researchers van Namen et al., (2019), the main means of managing MS is lifestyle changes based on education, regular exercise and healthy eating or the use of biologically active supplements. Many studies have confirmed the hypothesis that long-term improvements for people with MS depend on constant adherence to lifestyle changes. (Peiris et al., 2021; Peiris et al., 2023b). Adults with metabolic syndrome performed less objectively measured physical activity and had lower health literacy levels than those without metabolic syndrome. Perhaps a broader approach to therapy should be considered in community rehabilitation, where patients presenting for rehabilitation with a variety of conditions are likely to benefit from lifestyle assessment and intervention (Peiris et al., 2023a).

Based on recent systematic reviews and meta-analyses, Marcos-Delgado et al. (2021); Parameshwar et al. (2021), which included RCTs up to 2019, found that lifestyle interventions significantly improved a person's quality of life, but data on the effects of interventions on individual components of quality of life were limited. Thus, this issue has not yet been sufficiently studied and requires further research to evaluate the impact of interventions on components of the quality of life of patients with metabolic syndrome, which led to the study.

The aim of the research. The purpose of the systematic review was to evaluate the impact of lifestyle interventions in adults with metabolic syndrome (MS) on health-related quality of life (HRQoL) and its physical, mental and social dimensions.

Research materials and methods Review

The study was conducted in accordance with the PRISMA Elements for Systematic Reviews and Meta-Analyses (PRISMA) (Page et al., 2021). The Predominant Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement, published in 2009, was developed to help systematic reviewers transparently report why a review was done, what the authors did, and what they found. The 2020 PRISMA Statement replaces the 2009 Statement and provides new reporting guidance that reflects advances in methods for identifying, selecting, evaluating, and synthesizing studies. PRISMA 2020 presents a 27-item checklist, an expanded checklist with detailed reporting guidelines for each item, an abstract PRISMA 2020 checklist, and reviewed flowcharts for the original and updated reviews. Using PRISMA 2020 will lead to more transparent,

complete and accurate reporting of systematic reviews, facilitating evidence-based decision making.

Data sources and search

Databases used were PubMed, Cochrane Library, EMBASE and Google Scholar. The search was conducted in February 2024. Articles published in open access since 2020 and limited to English and Ukrainian languages were selected. The terms: (metabolic syndrome) and (quality of life or HRQoL) and (intervention or management) were associated with Boolean operators. Only randomized clinical trials were included. All selected studies were approved by the relevant ethics committees, where participants signed an informed consent form and adhered to the provisions established by the Declaration of Helsinki.

The study was carried out in accordance with the research plan «Theoretical and methodological foundations of physical therapy and occupational therapy for organic and functional disorders of the organs and systems of the human body in health-care practice», 2021–2025 (state registration number 0121U110141).

Choice of research

The analysis of the search results and selection of studies was carried out independently by two authors. Initially, articles were selected by title. Disagreements were resolved through discussion. After selection was completed, one author verified compliance with the selection criteria outlined under the acronym PICO (Population, Intervention, Comparison, and Outcomes). The selection of studies was then independently re-checked by a second author (Fig. 1).

Inclusion criteria were: randomized clinical trials (RCTs), the study was conducted in adults (both sexes) who met at least four criteria for MC, a lifestyle intervention, and measuring HRQoL using a validated questionnaire. Based on the Cochrane Collaboration's risk of bias tool, only two RCDs were found to have a high risk of bias, and five had a low risk (table 1) (Higgins et al., 2011).

Deleting data

The collected data were as follows: type of intervention, control treatment, duration of the study (weeks), number of participants and gender distribution,

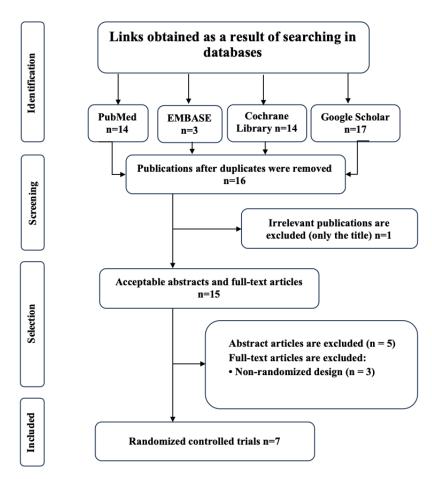


Fig. 1. Flowchart for selecting studies for a systematic review (PRISMA)

average age, content of the intervention, type of quality of life questionnaire, dynamics of indicators of physical and mental components of quality of life, social functioning and overall indicator with assessment reliability of the difference.

Research results and their discussion Description of the studies

The electronic search identified 48 publications (Figure 1). Among the papers found, there were 32 identical studies that were excluded from the analysis. One publication containing only the title of the article was also excluded. 15 reviewed abstracts and texts were retained. However, they included 5 abstracts without full text and 3 with designs different from RCTs. A detailed review of the seven RCTs selected for the systematic review included information on the intervention, study duration (weeks), number of participants and gender distribution, and mean age (table 2). The interventions selected ranged from comprehensive educational programs and lifestyle changes with controlled physical activity to the use of propolis as a dietary supplement. The duration of the studies varied from 8 to 48 weeks, and the average age of the participants – from 48.0 ± 8.0 to 66.9 ± 8.0 years. The total number of participants was 1108, 56% of whom were in the intervention groups. All studies included representatives of both sexes, with a ratio of 48% – men, 52% – women.

Content of interventions

The content of interventions used to influence quality of life was quite varied (table 3). Two behavioral educational programs were established, focused on achieving goals (with additional correction of nutrition) and using the principles of pedagogical autonomy, three physical activity programs (yoga, aerobic training and independent classes of moderate physical activity with telemonitoring), one passive intervention program (whole body vibration) and one program – the use of propolis dietary supplement.

Physical component of HRQoL

Changes in the physical component of quality of life were observed in all analyzed studies, but significant differences were established after interventions aimed at changing physical activity, even with a passive component (whole body vibration) (table 3). But in a study on the effects of aerobic training, Zupkauskiene et al., (2022) there were interesting dynamics in the physical component, where the results of the control group had large positive changes, significantly different from the intervention group. That is, the results of studies of the effect of aerobic exercise on this component are ambiguous. At the same time, changes in the assessment of the physical component of HRQoL did not occur in behavioral educational interventions. In one RCTs (propolis intervention), this component of HRQoL was not calculated.

Mental component of HRQoL

The mental component of HRQoL had slightly different dynamics and changed significantly in four studies (table 3). However, in only one study did this component differ between intervention groups (Achieving one's individual goals), and in three groups there was only a positive change in the mental component in the intervention group. In two studies, the expected changes in the mental component did not occur. Also in one RCTs (propolis intervention), the mental component of HRQoL was not calculated.

Social functioning as a component of HROoL

The social component turned out to be the most resistant to selected interventions. There were positive significant changes in only one study (physical activity supported by telemonitoring), and in other studies the result was unreliable (table 3). One of the RCTs had missing data.

Overall HRQoL assessment

In the fifth RCTs, data were missing, in one study there were positive changes (propolis consumption), and in the second (Whole Body Vibration) positive significant changes occurred in the control group (table 3).

Evaluation of quality indicators of selected RCTs

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Source	Randomization	Hiding distribution (selection bias)	Blindness	Incomplete result data	Selected research results	Risk of error
Paineiras-Domingos et al. (2020)	No	No	No	No	No	High
Funakubo et al. (2022)	Yes	No	No	No	Yes	Low
Haufe et al. (2020)	Yes	No	Yes	No	No	Low
Kempf et al. (2022)	Yes	No	Yes	No	Yes	Low
Sajjadi et al. (2023)	Yes	Yes	Yes	No	No	Low
Santos et al. (2022)	No	No	No	Yes	No	High
Zupkauskiene et al. (2022)	Yes	No	No	No	Yes	Low

Table 1

General characteristics of the RCTs included in the systematic analysis

Source	Intervention	Duration	Number of tested patients	Average age, years	Sex distribution
Paineiras-Domingos et al. (2020)	Whole body vibration	10 sessions 2 times a week	33 (17 – intervention group, 16 – control group)	Control group - 56.1±8.4, intervention group - 58.2±9.1	4 men and 29 women
Funakubo et al. (2022)	Laughter program (laughter yoga)	12 weeks	235 (intervention group – 117 and control group – 118)	66.9±8.0	37 men and 198 women
Haufe et al. (2020)	Physical activity	24 weeks	314 (160 – intervention group, 154 – control)	48.0±8.0	269 men and 45 women
Kempf et al. (2022)	Meal Replacement Lifestyle	48 weeks	263 (intervention group – 183 and control group – 80)	Control group - 50.1±9.8, intervention group - 51.5±9.0	98 men and 165 women
Sajjadi et al. (2023)	Propolis	12 weeks	62 (29 placebo group, 33 propolis group)	Placebo group - 53.86±5.60, propolis group - 54.27±6.58	5 men and 57 women
Santos et al. (2022)	Health Promo-tion Educatio-nal Program	24 weeks	61 (31 – intervention group, 30 – control)	49±7.6	5 men and 56 women
Zupkauskiene et al. (2022)	Aerobic training	8 weeks	140 (intervention group – 84 and control group – 56)	53.2 ± 6.8	63 men and 77 women

A systematic review of the seventh RCTs found that the effects of lifestyle interventions in adults with MS on components of HRQoL were inconsistent. Most programs had an impact on physical and mental components without a significant effect on social functioning. Features and different methods for assessing HRQoL scales made the effect of interventions on the overall HRQoL assessment unclear, since it was not calculated in most RCTs.

Improvement in HRQoL after interventions aimed at a healthy lifestyle has been established for the working population (Vargas-Martínez et al., 2021), for patients after cancer treatment (Leske et al., 2024). At the same time, the impact of various interventions on quality of life in patients with depressive symptoms (Gómez-Gómez et al., 2020) and chronic kidney disease (Neale et al., 2023) has been reported to be unclear. That is, the question of the impact of changes in lifestyle on its quality is very complex and has not been studied for many diseases.

One reason for the uncertainty of impacts may be the short duration of the studies. The design of such RCTs is not consistent with the timing of permanent changes in lifestyle modification, as such behavioral changes occur over months or years (Neale et al., 2023). In our study, four RCTs lasted less than 3 months. Perhaps increasing the duration of the study would provide more reliable results.

Findings from a preliminary meta-analysis by Marcos-Delgado et al. (2021), which was published

in 2021 and included seven RCTs from 2015 to 2019, showed that lifestyle interventions significantly improve a person's quality of life across all domains. However, according to them, this connection is still not well understood, which coincides with the conclusion of our studies, which also did not clarify this issue.

Three meta-analyses concluded that there is low-tomoderate-quality evidence that a multifaceted supervised lifestyle intervention improves multiple risk factors for metabolic syndrome and also reduces the prevalence of the disease (van Namen et al., 2019; Marcos-Delgado et al., 2021; Parameshwar et al., 2021). That is, the positive effects of the programs have been proven, but the impact on such an important indicator as HRQoL has had ambiguous evidence. In a meta-analysis by Marcos-Delgado et al. (2021) significant improvements were found in physical measures of HROoL scores for active intervention subjects compared with the group receiving general lifestyle information (Hedges' g 0.61, 95% confidence interval (CI) = 0,31–0,91). We obtained identical results in our study, but there was one RCTs T in which active lifestyle intervention led to less dynamics in the physical component than in the control group, in which the results were significantly better. Also in a meta-analysis by Marcos-Delgado et al. (2021) mental health-related quality of life was significantly improved in the intervention group compared to the control group (Hedges' g 0.84, 95% CI = 0.64-1.03), as was social functioning. Another meta-analysis by Parameshwar

Characteristics of interventions and changes in HRQoL indicators according to RCTs included in the system analysis

		- 1	Dynamics of the	Dynamics of the		2 2
Source	Contents of the intervention	Quality of Life Questionnaire	Dynamics of the physical component of health (before/after the intervention, significance of the difference)	mental component of health (before/ after intervention, significance of the difference)	Dynamics of social functioning (before/after intervention, significance of difference)	Dynamics of the overall assessment of QoL (before / after the intervention, significance of the difference
Paineiras- Domingos et al. (2020)	Whole body vibration	WHOQOL-BREF	control -20.21 ± 5.04 / $22.07 2.64 p = 0.15$ Intervention -20.35 ± 3.90 / 22.18 ± 4.39 , $p = 0.05$	control – 18.43 ± 4.63 / 19.64 4.70, p=0,12 Intervention – 18.65 ± 4.67 / 20.59 ± 5.16, p=0.04	control $- 8.28 \pm 3.64 /$ 9.35 ± 2.62 , p=0,41 Intervention $- 9.88 \pm 3.01 /$ 9.41 ± 2.69 , p=0,39	control -68.86 ± 15.15 / $9.74.86 \pm 10.49$, p=0,07 Intervention -73.53 ± 13.49 / 74.47 ± 10.09 , p=0,61
Funakubo et al. (2022)	The laughter program (rakugo) was carried out 8–10 times and consisted of 2 lectures on laughter yoga (30 minutes each) and rakugo classes (60 minutes each, 8–10 times)	SF-8	Intervention group – 46.6±7.8/48.5±6.7, control group – 46.8 ± 7.6 / 46.9 ± 8.3; p=0,04	intervention group – 48.8 ± 6.2 / 49.8 ± 6.5, control group – 49.3 ± 6.7 / 49.1 ± 7.3; p=0,22	intervention group – 48.3 ± 8.3 / 49.5 ± 8.1, control group – 48.7 ± 8.8 / 49.0 ± 8.1; p=0,48	Not assessed
Haufe et al. (2020)	150 minutes of moderate- intensity physical activity per week with telemonitoring and expectant control group	Short Form SF-36	$\begin{tabular}{ll} The difference is significant Short Form SF-36 & (p < 0.05) in the intervention group \\ \end{tabular}$	The difference is significant (p < 0.05) in the intervention group and in the control group $(p < 0.05)$	The difference is significant (p < 0.001) in the intervention group	Not assessed
Kempf et al. (2022)	Achieving your individual goals (e.g. weight loss, steps, healthy lifestyle changes). The intervention group additionally received a high-protein, low-glycemic meal replacement (Almased, Almased Wellness GmbH, Oberding, Germany). A 6-month intensive food replacement phase was followed by an observation phase until the 12th month.	SF-36	Changes are not reliable	Changes are reliable $(p < 0.0001)$	No data available	Not assessed
Sajjadi et al. (2023)	500 mg Iranian propolis extract	SF-36		Not assessed	Placebo group – 71.12 ± 29.71 / 76.72 ± 32.69, p=0.441, propolis group – 72.35 ± 28.94 / 74.95 ± 27.24, p=0,620; p=0.732	Placebo group -51.53 ± 15.93 / 54.16 ± 16.65 , p=0,222, propolis group -62.87 ± 15.36 / 73.02 ± 13.41 , p < 0,001; p < 0,001
Santos et al. (2022)	Seven month-long group workshops planned and based on a pedagogy of autonomy	SF-36	Not assessed	Changes are not reliable	Changes are not reliable	Not assessed
Zupkauskiene et al. (2022)	An aerobic training program, which consisted of exercise on a bicycle ergometer for 30-40 minutes/day, 5 days/week.	SF-36	intervention group – 73.57 ± 17.43 / 76.79 ± 17.43, p=0.02, control group – 73.69 ± 15.29 / 82.45 ± 14.23, p< 0.001; p= 0.031	intervention group – 74.43 ± 15.21 / 79.47 ± 13.73, p < 0,001, contro group – 76.41 ± 16.12 / 79.08 ± 13.81, p = 0.108; p= 0.299	intervention group – 84.97 ± 17.26 / 86.23 ± 16.09, p= 0.496, control group 86.89 ± 15.80 / 86.89 ± 15.80, p=0.006; p= 0.729	Not assessed

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et al. (2021) found positive changes only in the mental component of quality of life. What was not confirmed by the results of our study.

This study had limitations that must be considered to evaluate the results. The type of quality of life interventions varied greatly and it is difficult to say which interventions were more effective. In addition, the small number of RCTs and uneven methodologies for assessing HRQoL may also have influenced the findings. We believe that the results of the systematic review are interesting

in establishing the questionable dynamics of change in quality of life. This may further lead to an overestimation of the positive effects of lifestyle interventions on lifestyle quality, which were obtained in preliminary analyzes.

Conclusions

A systematic analysis found that lifestyle interventions according to the RCTs selected for this systematic review did not provide insight into these effects on HRQoL. However, further studies are needed to draw a stronger conclusion.

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