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Study Protocols

Comparison of conventional (face-to-face) and online approach in mindfulness-based chronic disease self-management interventions for older adults

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Abstract

Background: To compare the effectiveness between conventional (face-to-face) and online public health approaches focused on mental health, self-efficacy of health management and quality of life of older adults.

Design and methods: Participants will be 65+ residents of the city of Rijeka and the wider urban area and will be divided into three groups. The first group consists of participants who will be included in the conventional (face-to-face) form of public health intervention, the second group consists of participants who will be involved in online public health intervention and the third group consists of participants from the control group. A total of 450 participants will participate in a pretest-posttest non-equivalent groups design research, with 150 participants per group. A series of questionnaires will be administered to evaluate effect of the interventions on mental health, self-efficacy of health management and quality of life. Results of this research will provide insight into the effectiveness of the electronic way of implementing chronic disease self-management interventions compared to conventional (face-to-face) which can be useful to policy makers and public authorities in the organization and implementation of health policies.

Expected impact of the study for public health: This research will contribute to the definition, implementation and adaptation of future public health interventions related to mental health, self-efficacy of health management and quality of life in the context of various epidemiological situations such as the current one caused by the COVID-19 pandemic.

Introduction

Today's way of life requires the development of personal competencies and life skills that will maintain mental health and personal well-being. In cases where health conditions and/or diseases, as well as the inability to cope with daily stress and pressures, are related to personal competencies, habits, and behaviour, it is extremely important to encourage the individual to develop resilience through education to motivate the individual to change his or her lifestyle.

According to the World Health Organization, life skills are "the ability to behave adaptively and positively which enables individuals to effectively cope with the demands and challenges they face in everyday life". Life skills enable physical, mental, and emotional well-being and empower the individual to take actions to promote health and positive social relationships. The basic life skills are decision making, problem solving, creative and critical thinking, communication skills, social relationships, self-awareness, empathy and dealing with emotions and stress.¹

Mindfulness is a technique that originates from the Buddhist tradition and has become the subject of scientific research in the last three decades. Although mindfulness is not fully defined, this technique refers to the ability to observe one's own experience with intention, in the present moment and without condemnation which may affect the neuroplasticity of the brain and may improve cognitive functions.² It can also serve as a tool in the development of personal competencies and life skills or encourage the individual to develop resilience and change life habits. Lomas et al. describe that practicing mindfulness may increase the amplitudes of alpha and theta waves that positively affect individual's attention and relaxation.³

The World Health Organization defines mental health "as a state of well-being in which an individual realizes his potential, can cope

Significance for public health

Social distancing, curfews and quarantine during the COVID-19 pandemic led to a deterioration in mental health, especially in vulnerable population groups. Older adults were and are still greatly impacted by the pandemic in terms of mental health, socialization aspect and loneliness. Therefore, new approaches in public health interventions should be implemented. Innovative public health approaches related to resilience enhancement and chronic disease self-management in combination with modern technologies should be implemented and evaluated. Evidence-based results of this research will provide insight into the effectiveness of the electronic way of implementing public health interventions compared to conventional (face-to-face) which can be a useful tool to policy makers and public authorities in planning and adapting future mindfulness-based and chronic disease self-management interventions.

with normal life stresses, can work productively and is able to contribute to his community". The incidence of mental disorders, such as depression and anxiety, is increasing worldwide. Depression is the leading cause of disability in the world and has been diagnosed in more than 300 million people.⁴ As one of the approaches to improve mental health, various programs based on mindfulness are used, such as *Mindfulness-Based Cognitive Therapy* or *Mindfulness-Based Stress Reduction*. Several systematic reviews have shown that mindfulness can have a positive effect on daily stress, anxiety, and depression, as well as on specific psychiatric conditions such as *Attention Deficit and Hyperactivity Disorder*.⁵

Self-efficacy in health management is an important factor in the decision-making process, defining patterns of behaviour, coping with unpredictable situations, and developing cognitive abilities. General self-efficacy includes the ability to self-motivate, control emotional states, solve problems, and to be optimistic in fulfilling everyday tasks. Self-efficacy is closely related to a person's resilience to resist stressful situations that he encounters on daily basis, which leads to positive psychological and physical outcomes and easier achievement of goals. Higher levels of self-efficacy are associated with the practice of mindfulness, but also with life satisfaction⁶ and overall personal, social, and economic outcomes.

Quality of life, as it is defined by the World Health Organization, is "an individual's perception of their own position in life in the context of the culture and value systems that surround them and in relation to their goals, expectations, standards, and interests". It is a multidimensional concept that refers to the physical and mental health of the individual, his independence, social interactions, personal beliefs, and relationships with the surrounding environment. On the other hand, quality of life related to health represents indicators of personal perception and provides an evaluation of the effect of illness, disability, or other health condition on the well-being of the individual.⁷ Mindfulness-based public health interventions have shown a positive effect on quality of life⁸ and on the physical, mental, and social component of health.

Today's technologies enable the implementation of public health interventions in a much more accessible way and are available to everyone anywhere at any time. There is a wide range of mindfulness-based digital platforms and applications on the market that are becoming increasingly popular among general population. Although there is a belief that a conventional (face-to-face) approach gives better results, some research has shown that an electronic approach in interventions can lead to the same or even better outcomes.⁹

At the end of 2019, the city of Wuhan, became the centre of the spread of the COVID-19 pandemic caused by the SARS-CoV-2 virus. COVID-19 pandemic has significantly affected public health globally as it became a great burden on the health and social systems. The pandemic has led to a deterioration in mental health of the general population due to reduced social contact, the introduction of curfews and quarantine.¹⁰ Due to the new epidemiological situation and social distancing, it is necessary to define and introduce an electronic approach in the implementation of public health interventions with the aim of improving, primarily the mental health component.

The main goal of the research is to compare the effectiveness of conventional (face-to-face) and electronic mindfulness based public health interventions focused on mental health, the self-efficacy of health management and the quality of life of older adults. Additionally, the main hypothesis is that conventional (face-to-face) and electronic mindfulness based public health interventions equally and positively affect mental health, self-efficacy of health management and the quality of life of older adults.

Design and methods

The sample population will be divided in three groups. The first group consists of participants who will be included in the conventional (face-to-face) form of public health intervention, the second group consists of participants who will be involved in online public health intervention and the third group consists of participants from the control group. A total of 450 participants will be involved in a pretest-posttest non-equivalent groups design research, i.e., 150 participants per group.

The research will be conducted among the residents of the City of Rijeka and the wider urban area. For the purposes of the research, the City of Rijeka will be divided into three parts (western, central, and eastern part), while the remaining six municipalities will be divided into three groups with similar number of participants. The inclusion of participants in each group will be based on the geographical location of the participants and their family medical practitioners/community patronage nurses. First 450 patients that come to their general family medical practitioner or community patronage nurses and in regard to the inclusion and exclusion criteria, the research will be presented, and they will decide if they are willing to participate. In accordance with the research methodology, the participants will be given the option to participate either in control, face-to-face or online intervention. The control group will not be given the option to participate in the research after the interventions end.

The sample will be chosen in such a way to be representative of the inhabitants in the area of the city of Rijeka and the wider urban area. The sample size of 450 participants was determined according to a power calculation given the pretest-posttest non-equivalent groups design research. The obtained value for the number of subjects is 380 with a confidence interval of 95% and a level of statistical significance of $p < 0.05$ for continuous variables. Assuming that part of the participants will drop out throughout the research, the sample size conditions will be met.

Participants inclusion criteria are persons of both sexes older than 65 years; residence in the area of the city of Rijeka and the wider urban area; healthy people; persons with hypertension and/or type II diabetes; owning a smartphone, tablet, laptop, or desktop computer; possibility to participate in the research for a period of 6 months. On the other side, exclusion criteria are the following: persons who do not have permanent residence in the city of Rijeka and the wider urban area; inability to participate in the study for a period of 6 months (persons planning to travel for a longer period or terminally ill patients); persons who are homeless; persons suffering from mental illness (DSM IV); people with cognitive impairment; addicts to alcohol and other addictive substances.

The conventional (face-to-face) approach in conducting the seven-week workshop programme will be organized in a way that the participants will be divided into smaller groups, up to a maximum of 10 people, respecting the actual epidemiological measures. Workshops will be organized once a week for 2 hours. On the other hand, the online approach will be based on recordings of workshops that will be shared with participants via digital platforms. Contact with participants will be made via SMS, Viber, or WhatsApp.

To evaluate the effectiveness of the interventions in terms of general self-efficacy, chronic disease self-management, physical activity, nutrition, social support, stress, depression, sleep, fatigue, medication adherence, healthcare utilization and quality of life, *SEFAC Questionnaire*¹¹ will be used. The questionnaire was developed within the SEFAC project¹¹ and it consists of several, already used and validated questionnaires: *General Self-efficacy Scale*

(GES), *Short 6-item Version of the Chronic Disease Self-Efficacy Instrument* (CDSE-6), *The Physical Exercise Self-Efficacy Scale* (PESES), *The Nutrition Self-Efficacy Scale* (NSES), one question from the *International Physical Activity Questionnaire* (IPAQ), one question from the *AUDIT-C Questionnaire*, *3-Item Oslo Social Support Scale* (OSS-3), *10-Item Perceived Stress Scale* (PSS-10), *8-Item Patient Health Questionnaire Depression Scale* (PHQ-8), *Short Medication Adherence Questionnaire* (SMAQ), *12-Item Short-Form Health Survey* (SF-12), *EuroQol-5 Dimensions-5 Level Questionnaire* (EQ-5D-5 L), *Self-management Resource Center* (SMRC) *Health Care Utilization Questionnaire* and *Productivity Costs Questionnaire* (PCQ).

In addition to the above, the questionnaire also contains questions on the dynamics of physical activity, eating habits, sleep quality, fatigue and questions related to socio-demographic characteristics of participants.

To examine the effectiveness of online public health intervention on mental health in the context of the COVID-19 pandemic between the study and control groups, the *COVID-19 Pandemic Mental Health Questionnaire* (CoPaQ) will be used.¹²

Data will be collected at two time points: T0 (initial measurement) and T1 (measurement after 6 months). The collected data will be entered into tables formatted in MS Excel (Microsoft Corporation, USA) and statistically processed in Statistica 13.0. (TIBCO Software Inc., USA). Category data will be displayed by frequency (N) and relative frequency (%) and compared with the appropriate test for category data. Quantitative data will be presented by mean and scatter measures depending on the type of distribution tested by the Kolmogorov-Smirnov test. Accordingly, the hypotheses will be tested by appropriate parametric and nonparametric tests for independent and dependent samples. The validity of measuring instruments will be examined by factor analysis, reliability by the internal consistency method and will be expressed by the Cronbach's coefficient α . The results will be presented in tabular and/or graphical form. The level of statistical significance will be determined at $\alpha = 0.05$.

This research will be conducted in accordance with all applicable guidelines, which aim to ensure the proper conduct of research and the safety of persons participating in this research while respecting the Fundamentals of Good Clinical Practice. The research will ensure respect for basic ethical and bioethical principles - personal integrity (autonomy), justice, charity and innocence - in accordance with the *Nuremberg Code* and the latest revision of the *World Medical Association Declaration of Helsinki*, the *Health Care Act of the Republic of Croatia* (OG 158/08, 71/10, 139/10, 22/11, 84/11, 12/12, 35/12, 70/12, 82/13, 100/18 and 125/19), the *Patients' Rights Act of the Republic of Croatia* (OG 169/04, 37 / 08) and *Regulation (EU) 2016/679* of the European Parliament and of the Council of April 27, 2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

The study has received ethical approvals from the Ethics Committee of University of Rijeka, Faculty of Medicine (class: 003-08/20-01/91; registry number: 2170-24-09-8-20-3) and as well as from the Ethics Committee from the Community Health Centre of Primorje-Gorski Kotar County, Rijeka, Croatia (registry number: 01-47/2-2-21).

Expected impact of the study for public health

Participants engaged in the conventional (face-to-face) and electronic public health intervention will participate in a seven-week workshop program. These workshops were developed

through the SEFAC project,¹¹ mainly by the *Istituto per Servizi di Ricovero ed Assistenza agli Anziani* research team from Treviso, Italy, using the theoretical framework which includes the salutogenic and person centred approach, positive psychology, change behaviour theory based on the Transtheoretical Model, mindfulness and the GROW coaching model.¹³ Additionally, the workshop program was also enriched by using the experience from two existing evidence-based programs: *The Chronic Disease Self-Management Programme* (CDSMP)¹⁴ and the *Mindfulness-based Living Program*.¹⁵ *The Chronic Disease Self-Management Programme* (CDSMP) was developed at Stanford University, and it aims to build participants' self-confidence in managing their health and keep them active and involved in decision-making in their own lives. On the other side, the *Mindfulness-based Living Program*, developed by the *United Kingdom Mindfulness Association* and based on the *Mindfulness-Based Cognitive Therapy* and the *Mindfulness-Based Stress Reduction Programme*, refers to an eight-week program that develops skills and knowledge for practicing mindfulness.

The aim of the seven-week workshop program, which will be led by trained workshop leaders, is to improve behavioural change of both older adults at risk and those suffering from major chronic diseases, making them more aware of their habits and lifestyle, encourage them in learning new skills for improvement of self-efficacy, self-esteem, and the ability of self-managing their health. Additionally, the program of the workshops will encourage the participants in developing resilience skills and contribute to the reduction of stress level, anxiety and depression. The intervention for older adult patients that are in risk of developing a major chronic disease aims at decreasing the risk factors that are modifiable: obesity, unhealthy diet, physical inactivity, harmful levels of alcohol consumption, tobacco use, stress, anxiety and depression.

On the other side, the intervention for participants that have a major chronic disease is intended to encourage them in self-managing and monitoring their disease, empower them and increase their self-efficacy as well as adopt healthier lifestyles with regard to modifiable factors in order to achieve better health outcomes and to save system resources by a decreased and more effective utilization of services. This program can ensure a sustainable impact, saving costs from the perspective of the citizens at risk for or with major chronic diseases such as cardiovascular diseases and type II diabetes, the health system itself and provide evidence to health policy makers in order to propose reforms towards more effective and efficient models of chronic care prevention and management.

At the beginning of the research, databases will be created in accordance with the used methods (questionnaires) and the participants will be divided into three groups (face-to-face, online and control group). Prior to the start of the conventional and electronic form of the intervention, the potential participants will be fully informed about the study and will be invited to fill out the Informed consent form. Participants who provided informed consent will be invited to complete the questionnaires (first measurement; T0). This will be followed by workshops that will be organized in a conventional (face-to-face) and in an electronic way. In both cases, workshops will be held once a week, for 7 weeks. Six months after the workshops are over, all participants will fill out the same questionnaires with the addition of questions that will evaluate the satisfaction of workshop participants with the implemented program (second measurement; T1).

This research will contribute to the definition, implementation and adaptation of future public health interventions related to mental health, health management self-efficacy and quality of life in the background of various epidemiological situations such as the

current one caused by the COVID-19 pandemic. Evidence-based results of this research will provide insight into the effectiveness of the electronic way of implementing public health interventions compared to conventional (face-to-face) which can be useful to policy makers and public authorities in the organization and implementation of health policies. The ultimate goals of this research is to improve accessibility of the public health interventions, the health security of citizens, promote health and a healthy lifestyle, and provide, not only a systems' framework for thinking about behavioural change as an outcome of community-based interventions, but also a framework for thinking about healthy communities.

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Conflict of interest: The authors declare no conflict of interest with respect to the research, authorship, and/or publication of this article.

Availability of data and materials: The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate: The study has received ethical approvals from the Ethics Committee of University of Rijeka, Faculty of Medicine (class: 003-08/20-01/91; registry number: 2170-24-09-8-20-3) as well as from the Ethics Committee from the Community Health Centre of Primorje-Gorski Kotar County, Rijeka, Croatia (registry number: 01-47/2-21).

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