STUDY PROTOCOL:

Effects of yoga on wellbeing and healthy ageing: a randomized controlled trial (FitForAge).

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BACKGROUND

Due to the ageing of populations worldwide the burden of disability is increasing. Thus, it is important to develop interventions that improve healthy ageing, reduce disability onset and enhance life quality. Physical activity can promote healthy aging and help maintain independence, yet many older adults do not reach the recommended activity levels. Yoga is a form of physical activity that aims to improve physical and psychological health, and may be suitable for older adults. Research indicates positive effects of yoga on several health-related outcomes, however, empirical studies examining the benefits of yoga on wellbeing among the elderly remain scarce.
AIM

The aim of this study is to explore the effects of a 12-week yoga program on health and wellbeing among physically inactive older adults, compared to aerobic exercise and non-active controls (wait-list).

METHOD

Study design

Three group parallel randomized controlled trial (RCT) comparing yoga, aerobic exercise and non-active controls. Assessments will be performed at baseline and 12-week follow-up. The goal is to recruit 180 participants.

Participants

To be eligible for this study, participants must reside in Stockholm, be 65-85 years, be fluent in Swedish, and be willing to participate. Exclusion criteria: physical or cognitive deficit/disability, extensive surgery the past year, uncontrolled blood glucose or blood pressure, irregular pulse or glaucoma, recently diagnosed for a serious mental illness (e.g. psychosis or bipolar disorder), indicating acute signs of suicidality (e.g. recent and ongoing thoughts of death/suicide), currently or recently (past three months) engaged in regular structured exercise, on average two days per week or more.

Randomization and blinding

Participants will be randomized into one of the three groups. The randomization list will be computer generated, performed externally by a statistician at the Karolinska Institute and kept confidential. The allocation sequence will be transferred into separate sealed envelopes. Treatment allocation will not be concealed for study participants nor the research assistant. A different research assistant will be responsible for the follow-up of study participants, and blinded to group allocation.

Interventions

Participants randomized to the yoga group will receive a free 3-month membership to a fitness centre with multiple locations across Stockholm. The centre offers senior yoga, designed for older adults, aiming to improve flexibility, core strength and balance. The classes are considered suitable and safe for most older adults and each class is 60 minutes long. Participants will be encouraged to attend classes three times weekly during the 12-week period and will furthermore be encouraged to perform the yoga postures at home at least once a week. To confirm adherence, participants will be asked to complete a weekly exercise diary, and attendance at the yoga classes will be recorded electronically when participants enter the fitness centre. The research team will not be present during the yoga classes, which will also be available to adults who are not part of the study.

Participants in the aerobic exercise group will receive a fitness centre membership card valid for 3 months, and encouraged to participate in light to moderate aerobic exercise classes designed for older adults (e.g. cycling/spinning, walking, dancing and aerobics). The location, frequency and duration of training will be the same as the yoga group (e.g. 3 times per week for about 60 minutes each session) and all participants will be asked to complete a weekly
exercise diary. Thus, the two groups will be matched in terms of exercise frequency, context, and opportunities to socialize while exercising.

Participants randomized to the non-active comparison group will be wait-list controls. At inclusion, they will be instructed to continue their daily activities as usual (e.g. without engaging in regular structured exercise). As an incentive, these participants will also receive a gym card valid for three months when they attend their follow-up (12 weeks).

All participants in the exercise groups will meet with a personal trainer in the beginning, middle and end of the 12 weeks of the study. All participants that attend follow-up will receive a 20 % discount on a fitness centre membership card.

Outcomes

The primary outcome variable is subjective wellbeing, measured using Life Satisfaction Index (LSI-Z) and Satisfaction with Life Scale (SWLS).

Secondary outcomes:

- Physical activity/sedentary behaviour: International Physical Activity Questionnaire, Simple Physical Activity Questionnaire
- Mobility/fall risk: Berg Balance Score
- Cognition: Verbal fluency
- Cardio-metabolic risk factors: Blood pressure, resting heart rate, Body Mass Index and Waist-Hip Ratio, complete blood count, blood glucose, blood lipids, saliva cortisol, Heart Rate Variability
- Depression: Geriatric Depression Scale
- Anxiety: State-Trait Anxiety Y2
- Mood: Profile of Mood States
- Stress: Perceived Stress Scale
- Pain: Brief Pain Inventory Short Form
- Sleep quality: Insomnia Severity Index
- Social support: Interview Schedule for Social Support

Statistical method and power calculation

Based on a 6-month trial comparing the effects of beginners Iyengar yoga with light walking (Oken et al, 2006), a total sample of 180 participants is estimated with an expected standardized mean difference of 0.2 on the primary study outcome (wellbeing) favouring the yoga group compared to aerobic exercise (80% power, two-tailed significance for the primary between-group comparisons and 1:1:1 allocation). This calculation includes a drop-out rate of 20 %. Intention-to-treat analyses will be performed to explore the effects on the primary outcome.

ETHICAL CONSIDERATIONS

The study is approved by the regional ethics committee in Stockholm (Regionala Etikprövningsnämnden, number 2017/1862-31/2). Study amendments will be sent to the regional ethics committee for evaluation. The study will be conducted in accordance with the protocol, Good Clinical Practice as well as the requirements from the Regional Ethics Committee.
Every potential participant will be informed about the aim, methods, procedure and confidentiality prior to participation, verbally and in writing. All participants must voluntarily agree to participate and are free to withdraw from the study at any point. Written, informed consent will be obtained from all participants.

**FUNDING**

This study has received funding from the Swedish Research Council for Health Working Life and Welfare (FORTE).

**EXPECTED START DATE**

January 2019

**EXPECTED FINISHING DATE**

January 2020

**EXPECTED REPORTING DATE**

January 2021