Statistical Analysis Plan (SAP)

Official Title: The Effect of MediYoga on Quality of Sleep, Blood Pressure and Quality of Life Among Older People: A Randomized Controlled Study

ClinicalTrials.gov ID: NCT06553820

Version: 2.0

Date: 27 July 2026

Prepared by: Katrine Vollbrecht Amdi

Department of Cardiology, Herlev and Gentofte Hospital

1. Introduction

This Statistical Analysis Plan (SAP) describes the planned statistical analyses for a three-arm, parallel-group randomized controlled trial evaluating the effects of app-based MediYoga on sleep quality, blood pressure, health-related quality of life, and symptoms of anxiety and depression among adults aged 65 years or older with self-reported hypertension. Participants were randomized to one of three groups: MediYoga 20 minutes twice weekly, MediYoga 40 minutes twice weekly, or usual care. Outcomes were assessed at baseline, immediately after the 10-week intervention, and at 3-month follow-up. Blood pressure was additionally measured twice weekly throughout the intervention period.

The primary analysis will test the effect of MediYoga at the end of the 10-week intervention, which represents the pre-specified primary endpoint of the trial. Outcomes measured at the 3-month follow-up will be analysed separately as secondary analyses to evaluate maintenance of treatment effects.

This SAP is based on protocol version 1.0 (13 November 2024)[1] and the ClinicalTrials.gov registration (NCT06553820). It specifies all planned analyses before completion of the final statistical analyses.

2. Study objectives and hypotheses

Primary objectives

To test whether app-based MediYoga improves sleep quality, measured by Pittsburgh Sleep Quality Index (PSQI), after the 10-week intervention compared with usual care among older adults with hypertension

Secondary objectives

Secondary objectives are to test whether MediYoga improves:

- Sleep quality (PSQI) at 3-month follow-up.
- Systolic blood pressure (SBP) at 10 weeks and 3-month follow-up.

- Diastolic blood pressure (DBP) at 10 weeks and 3-month follow-up.
- Anxiety symptoms measured by HADS-A at 10 weeks and 3-month follow-up.
- Depressive symptoms measured by HADS-D at 10 weeks and 3-month follow-up.
- Health-related quality of life measured by the SF-12 Physical Component Score (PCS) and Mental Component Score (MCS) at 10 weeks and 3-month follow-up.

Hypotheses

The primary hypothesis is that participants allocated to either the MediYoga 20-minute group or the MediYoga 40-minute group will have lower PSQI global scores after the intervention compared with participants allocated to usual care.

Secondary hypotheses are that MediYoga will improve blood pressure, anxiety symptoms, depressive symptoms, and health-related quality of life compared with usual care.

3. Analysis populations

Intention-to-treat population

The primary analysis will follow the intention-to-treat (ITT) principle. All randomized participants will be analysed according to their allocated treatment group, regardless of adherence to the intervention or protocol deviations.

Per-protocol population

A per-protocol (PP) analysis will be performed as a sensitivity analysis. For the intervention groups, the PP population will include participants who completed at least 80% of the prescribed MediYoga sessions (≥16 of 20 sessions) and provided outcome data at the 10-week assessment. Participants meeting this adherence criterion in each MediYoga group will be compared with all participants in the control group with available outcome data at the 10-week assessment.

4. Statistical principles

Continuous outcomes will be analysed using baseline-adjusted linear regression models. Binary outcomes, if applicable, will be analysed using baseline-adjusted logistic regression models. Outcomes measured at the 3-month follow-up will be analysed separately as secondary analyses to evaluate the maintenance of treatment effects.

Baseline characteristics will be summarised descriptively by randomized group. No formal statistical testing of baseline differences will be performed.

Results will be presented as adjusted mean differences (continuous outcomes) or odds ratios (binary outcomes), with 95% confidence intervals and two-sided p-values. Statistical significance will be assessed using a two-sided significance level of 0.05.

5. Analysis of the primary outcome

The primary outcome is the Pittsburgh Sleep Quality Index (PSQI) global score at the end of the 10-week intervention. The primary analysis will use a linear regression model adjusted for baseline PSQI, with randomized treatment group included as a three-level categorical variable (control, MediYoga 20 minutes, and MediYoga 40 minutes).

The primary comparisons will be:

MediYoga 20 minutes versus control.

MediYoga 40 minutes versus control.

If both intervention groups demonstrate superiority over control for the primary outcome, a planned exploratory comparison between the two intervention groups (MediYoga 20 minutes versus MediYoga 40 minutes) will also be performed. Treatment effects will be reported as adjusted mean differences with 95% confidence intervals and two-sided p-values.

6. Analysis of secondary outcomes

Secondary outcomes include PSQI global score at the 3-month follow-up, systolic blood pressure (SBP), diastolic blood pressure (DBP), HADS Anxiety (HADS-A), HADS Depression (HADS-D), SF-12 Physical Component Score (PCS), and SF-12 Mental Component Score (MCS).

Continuous secondary outcomes will be analysed using the same linear regression modelling approach as described for the primary outcome, with adjustment for the corresponding baseline value.

Analyses will be performed separately at the end of the 10-week intervention and at the 3-month follow-up. Treatment group will be included as a three-level categorical variable (control, MediYoga 20 minutes, and MediYoga 40 minutes). Planned contrasts will compare MediYoga 20 minutes versus control and MediYoga 40 minutes versus control.

The results of the secondary outcome analyses will be interpreted in the context of the primary outcome. Given the number of planned comparisons, statistically significant findings for secondary outcomes will be interpreted with caution, particularly if the primary outcome is not statistically significant.

7. Missing data

Missing outcome data will be handled using multiple imputation under the missing at random (MAR) assumption.

The primary analyses of both the primary and secondary outcomes will be based on the imputed datasets.

Complete case analyses will additionally be performed as sensitivity analyses to assess the robustness of the findings.

8. Sensitivity analyses

Sensitivity analyses will include:

- Complete case analyses of the primary and secondary outcomes, comparing the results with those obtained from the primary analyses based on multiple imputation.
- Per-protocol analysis of the primary outcome comparing participants in each MediYoga intervention group who completed at least 80% of the prescribed intervention sessions (≥16 of 20 sessions) with all control participants with available outcome data at the 10-week assessment.
- To assess potential selection bias related to adherence, baseline characteristics of participants in the MediYoga intervention groups with ≥80% adherence will be compared descriptively with those of participants with <80% adherence.

9. Interpretation of secondary outcomes and multiplicity

The primary analysis of the trial is the comparison of the PSQI global score at the end of the 10-week intervention.

Given the number of planned comparisons across secondary outcomes and follow-up time points, results from secondary analyses will be interpreted with caution. Particular emphasis will be placed on the primary outcome when interpreting the overall findings of the trial.

Statistically significant findings for secondary outcomes will be considered supportive and interpreted in the context of the primary outcome rather than as definitive evidence of treatment effectiveness.

10. Statistical software

All statistical analyses will be performed using R (R Foundation for Statistical Computing, Vienna, Austria). The R version and relevant packages used for the analyses will be reported in the final study report and any resulting publications.

11. Presentation of results

Baseline characteristics will be presented descriptively by randomized group. Continuous variables will be summarised using means and standard deviations or medians and interquartile ranges, as appropriate. Categorical variables will be summarised using frequencies and percentages.

Results from the primary and secondary analyses will be presented as adjusted effect estimates with 95% confidence intervals and two-sided p-values. No formal statistical testing of baseline differences between randomized groups will be performed.

Participant flow through the trial will be presented using a CONSORT flow diagram.

References

1. Risom SS, Amdi KV, Wahlström M, Rasmussen TB, Sharma S, Kabir ZN, et al. The effect of MediYoga on sleep-quality, blood pressure and quality of life among older people with hypertension: study protocol of a pragmatic randomized controlled trial. BMC Complement Med Ther. 2025;25. https://doi.org/10.1186/s12906-025-04846-6.

Planned tables

1. Table 1. Baseline characteristics
2. Table 2. Primary outcome: PSQI at 10 weeks
3. Table 3. Secondary outcomes at 10 weeks
4. Table 4. Secondary outcomes at 3-month follow-up
5. Table 5. Sensitivity analyses for the primary outcome

Supplementary Table S1. PSQI component analyses-
Supplementary Table S2. Baseline characteristics according to intervention adherence

Table 1

Characteristic	Control (n = 60)	MediYoga 20 min (n = 60)	MediYoga 40 min (n = 60)	Total (n = 180)
Demographic characteristics				
Age (years)				
Sex				
Female				
Male				
Educational level				
Primary/Basic				
Secondary/High school				
Vocational				
Short-cycle higher education				
Medium-cycle higher education / Bachelor				

Long-cycle higher education / Master & PhD	
Family status	
Married/cohabiting	
Relationship	
Single	
Widow	
Occupation	
Employed	
Retired	
Clinical characteristics	
Systolic blood pressure (mmHg)	
Diastolic blood pressure (mmHg)	
Height (cm)	
Weight (kg)	
BMI (kg/m²)	
Medication	
Beta-blocker	
ACE inhibitor	
Angiotensin II receptor blocker	
Calcium channel blocker	
Thiazides	
Diuretics	

Antithrombotic medication	
Lipid-lowering medication	
Number of antihypertensive drugs	
0 drugs	
1 drug	
2 drugs	
≥3 drugs	
Number of comorbid conditions	
0 comorbidities	
1 comorbidity	
2 comorbidities	
≥3 comorbidities	
Values will be presented as mean ± SD or n (%), as appropriate.	

Table 2. Primary outcome: PSQI global score at 10 weeks

Comparison	Adjusted mean difference	95% Confidence Interval	P-value
MediYoga 20 min vs Control			
MediYoga 40 min vs Control			

MediYoga 20 min vs MediYoga 40 min*

Note. *This comparison will only be performed if both MediYoga intervention groups demonstrate superiority compared with the control group for the primary outcome, as prespecified in the Statistical Analysis Plan

Table 3. Secondary outcomes at 10 weeks

Outcome	Control Mean (SD)	MediYoga 20 min Mean (SD)	MediYoga 40 min Mean (SD)	Adj. mean diff. 20 vs Control	95% CI	P-value	Adj. mean diff. 40 vs Control	95% CI	P-value
Systolic blood pressure (SBP)									
Diastolic blood pressure (DBP)									
HADS Anxiety (HADS-A)									
HADS Depression (HADS-D)									

SF-12 Physical Component Score (PCS)									
SF-12 Mental Component Score (MCS)									

Table 4. Secondary outcomes at 3-month follow-up

Outcome	Control Mean (SD)	MediYoga 20 min Mean (SD)	MediYoga 40 min Mean (SD)	Adj. mean diff. 20 vs Control	95 % CI	P-value	Adj. mean diff. 40 vs Control	95 % CI	P-value
PSQI global score									
Systolic blood pressure (SBP)									
Diastolic blood pressure (DBP)									

HADS Anxiety (HADS-A)						
HADS Depression (HADS-D)						
SF-12 Physical Component Score (PCS)						
SF-12 Mental Component Score (MCS)						

Table 5. Sensitivity analyses for the primary outcome (PSQI at 10 weeks)

Analysis	MediYoga 20 min vs Control Adjusted mean difference	95% CI	p-value	MediYoga 40 min vs Control Adjusted mean difference	95% CI	p-value
Multiple imputation (primary analysis)						
Complete case analysis						
Per-protocol analysis (observed 10 week						

outcome data)

Supplementary Table S1. PSQI component analyses

Outcome	Control Mean (SD)	MediYoga 20 min Mean (SD)	MediYoga 40 min Mean (SD)	Adj. mean diff. 20 vs Control	95% CI	P-value	Adj. mean diff. 40 vs Control	95% CI	P-value
Subjective sleep quality									
Sleep latency									
Sleep duration									
Habitual sleep efficiency									
Sleep disturbances									
Use of sleep medication									
Daytime dysfunction									
Good sleepers (PSQI ≤5)									

Note. For 'Good sleepers (PSQI ≤5)', report odds ratios instead of adjusted mean differences if analysed as a binary outcome.

Supplementary Table S2 Baseline characteristics according to intervention adherence

Characteristic	MY20≥80% adherence	MY20 <80% adherence	MY40 ≥80% adherence	MY40 <80% adherence
N				
Age				
Sex				
Baseline PSQI				
SBP				
DBP				
BMI				
HADS-A				
HADS-D				
SF-12 PCS				
SF-12 MCS				
Number of antihypertensive drugs				
Number of comorbid conditions				