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THE MEDITAGING STUDY:

A Protocol of an RCT verifying the MBSR Effects on Older Portuguese-speaking Migrants

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MEDITAGING Study: *Mindfulness training on aging: the effects of mindfulness based-stress reduction in older Portuguese-speaker migrants residing in Luxembourg*

- World population aging
- Global immigration and vulnerability of the older migrants
- Immigration in Luxembourg

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Mindfulness-Based Stress Reduction (MBSR)

Health Promotion Program (HPP)

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Aims

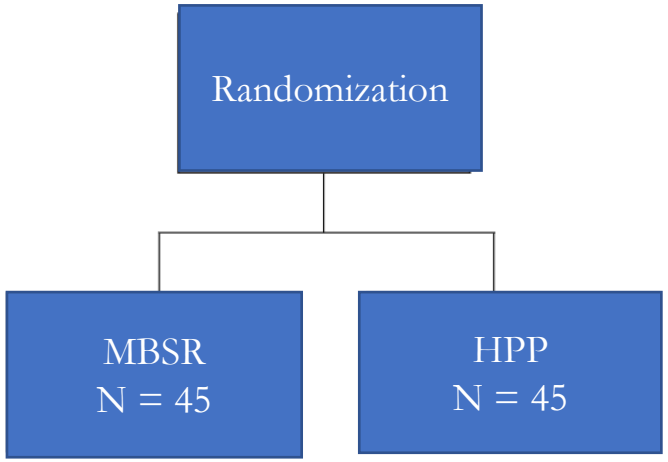
- To quantitatively and qualitatively evaluate and compare the effects of the MBSR in older Portuguese-speaking migrants in Luxembourg in comparison to a health promotion program, immediately after interventions and around two-months thereafter.

- A monocentric, randomized, double-blinded (assessor and participants blind) controlled superiority clinical trial with two parallel arms (with a 1:1 ratio).

METHODS

Participants:

- 90 Portuguese-speaking migrants (age ≥55 years older)
- Participants have no major neurological or psychiatric disorders or current unstable illness



Eligibility criteria

Inclusion	Exclusion
- Being a Portuguese-speaking migrant, residing in the Grand-Duchy of Luxembourg or the Greater Region; - Age: 55 years old or older; - Mastery of spoken, written, and reading Portuguese; - Subjects without cognitive impairment - verified through the MMSE, cut-off of < 22 adopted since most participants are expected to have a low education level (Kochhann et al., 2010). - Full capacity of consent.	- Previous (up to 3 years before) or current weekly participation in meditation, yoga, or mindfulness-based interventions; - Concomitant participation in another kind of group interventions (e.g., cognitive training, psychological therapy); - Attendance in psychological consultation; - Severe hearing or visual impairment (not corrected); - Severe medical condition requiring intensive medical care that makes it difficult to participate in the group sessions. - Refusal to sign the informed consent; - Diagnosis of dementia; - Clinical neurodegenerative illness, psychotic disorder, unstable psychiatric condition which makes it difficult to participate in group works, posttraumatic stress disorder or history of trauma, acute psychosis, mania, suicidality, or substance abuse within the last 6 months (cutoff: 2 points at the Adult DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure).

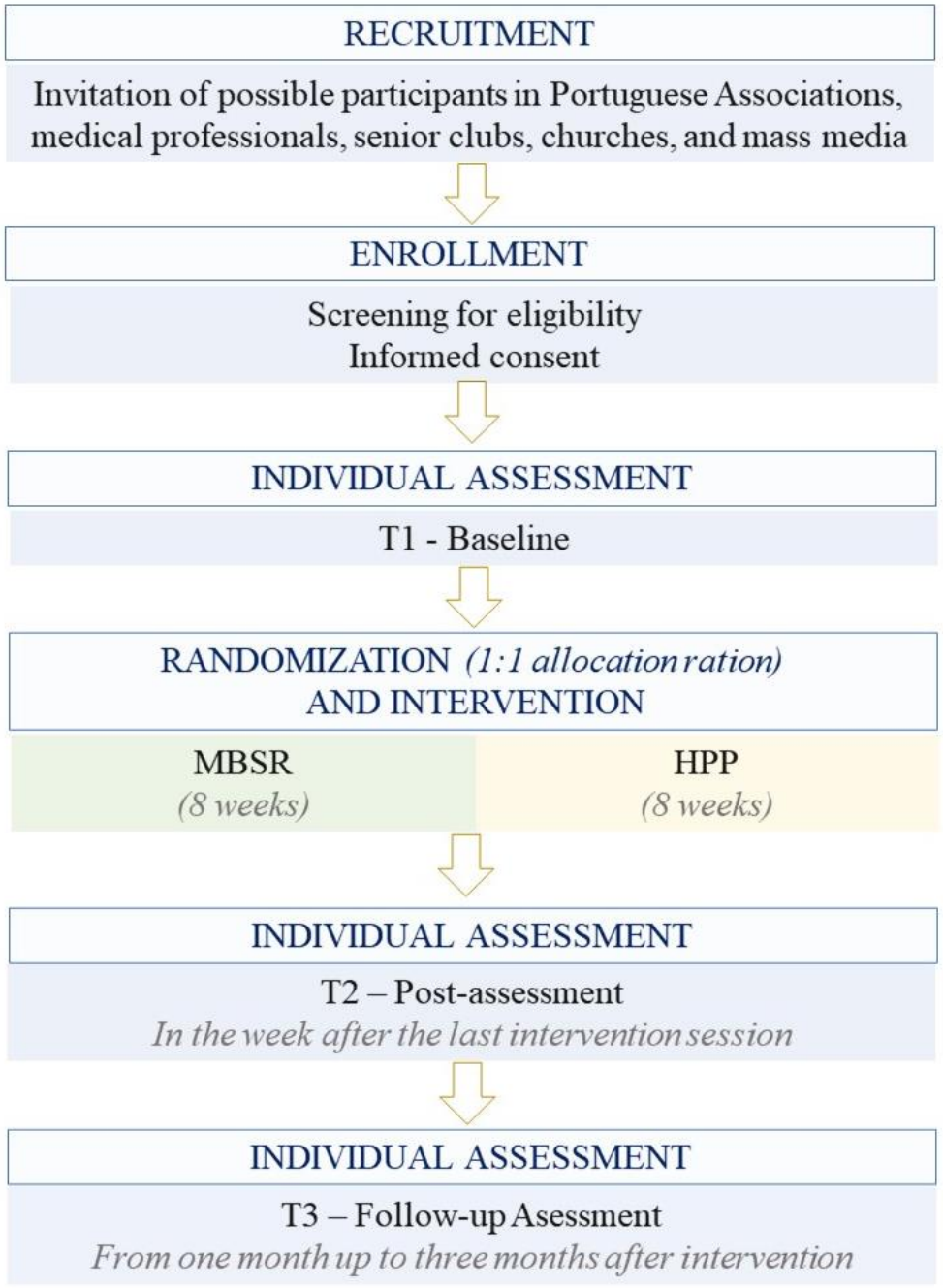

RECRUITMENT
Invitation of possible participants in Portuguese Associations, medical professionals, senior clubs, churches, and mass media
ENROLLMENT
Screening for eligibility
Informed consent
INDIVIDUAL ASSESSMENT
T1 - Baseline
RANDOMIZATION (1:1 allocation ration) AND INTERVENTION
MBSR
(8 weeks)
HPP
(8 weeks)
INDIVIDUAL ASSESSMENT
T2 – Post-assessment
In the week after the last intervention session
INDIVIDUAL ASSESSMENT
T3 – Follow-up Asessment
From one month up to three months after intervention

Table 2. Screening and assessment measures

Measures	Screening	Baseline (T1)	Post intervention (T2)	Follow-up (T3)
Demographic and health questionnaire	x			
MMSE	x		x	x
DSM-5 Self-Rated Level 1 Cross-Cutting Symptom	x			
Saliva sample for cortisol analysis		x	x	
TMT		x	x	x
Stroop color word task		x	x	x
Letter-number sequencing		x	x	x
PSQI		x	x	x
PPS		x	x	x
MAAS		x	x	x
GAI		x	x	x
GDS-5		x	x	x
Heart rate variability		x	x	x
Semi-structured interviews		x	x	x

- **Primary outcome:** executive functioning
- **Sencondary outcomes:** general cognitive ability, sleep quality, perceived stress, depression, anxiety, mindfulness trait, cortisol level, and heart rate variability
- **Moderator variables:** demographic factors, such as gender and educational level, as well as number of attended sessions, stress, depression, mindfulness trait, anxiety, cortisol level, and sleep quality

- **Hypothesis:** *the MBSR group will present gains in cognitive tasks and stress relief and these gains will be higher than in the control group (health promotion program)*

- **Adverse effects:** Positive and Negative Affect Schedule (PANAS) and a Visual Analog Scale (VAS) / qualitative interview

- **Statistical analyses:** modified intention-to-treat (i.e., participants that participated in at least three group-sessions and have at least one post-intervention assessment)

  - Mixed-effect regression models with maximum likelihood estimation (group*time)

- **Qualitative analysis**: interviews recorded in audio and transcribed in Portuguese.
  - *Content analysis* using the NVivo 12 software (Malterud, 2012; QSR International Pty Ltd, 1999)

Limitations

- Dropout rate
  - since 25.2% of the Portuguese immigrants plan to commute between Portugal and Luxembourg (Albert et al., 2016)
- Adherence and registration of the home practices
- Exclusion due to illiteracy

DISCUSSION

- Current status: finishing data collection
- Preliminary analysis:
  - ↑ anxiety symptoms (M_{GAI} = 9.65, SD = .713) than samples from Portugal (M = 3.49, SD =.506) $p < .001$.
- Social impact: integration of participants in Senior Services.
  - Spontaneous reporting of subjective benefits by participants and institutions.
- Importance of the project since in high-income countries, there are few programs promoting health in disadvantaged populations (Shahidi et al. 2019)

Thank you!

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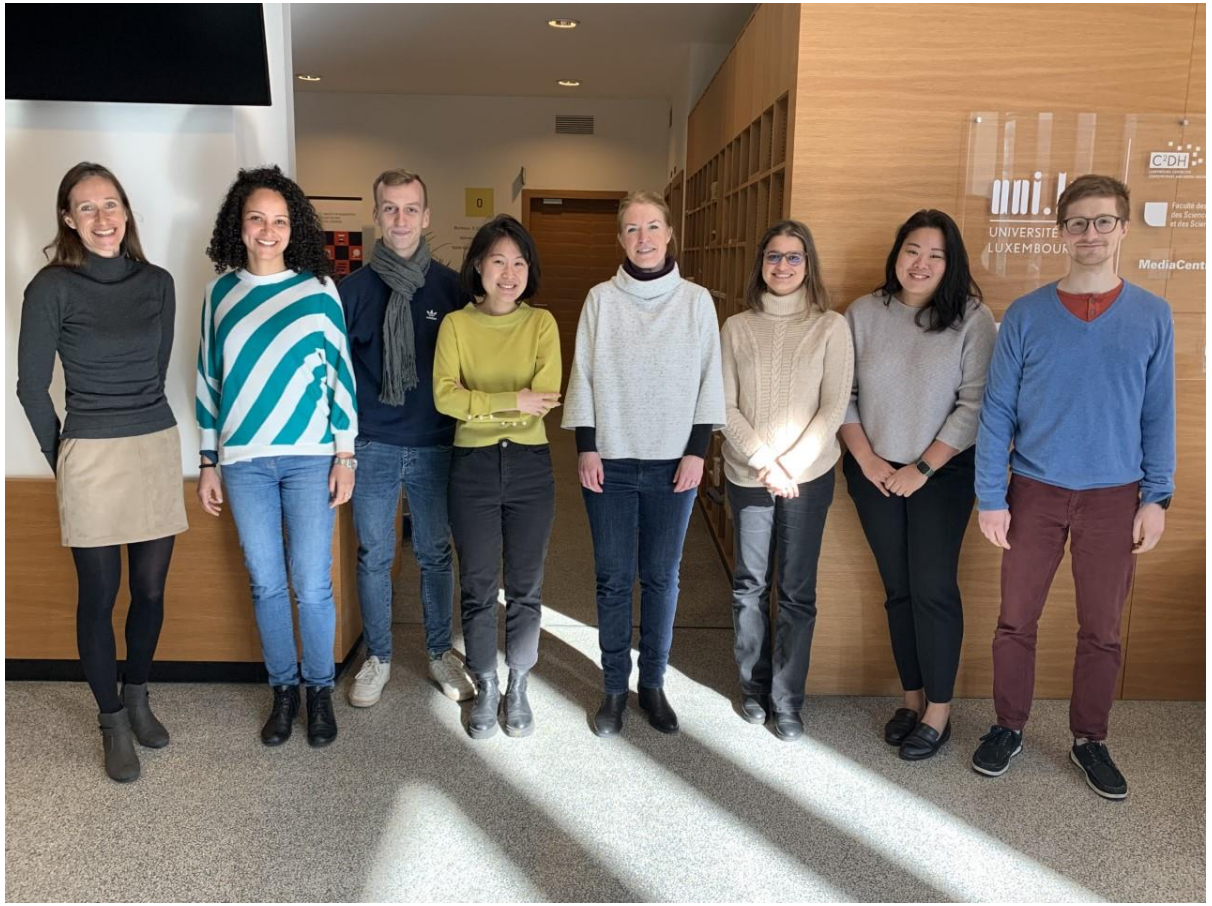

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